

EXHIBIT 35

Food and Drug Administration Office of Regulatory Affairs
Collection Report
For Sample Number: 453913
This is a mechanism to accurately reproduce the original electronic record as of 03/01/2010.

Flag	Flag Remarks				
Episode Number	Origin Domestic	Basis Other-Survn	Sample Type Official	FIS Smpl Num 0885198	Status Completed
FEI 1610608 2244683	Date Collected 02/15/2008	Product Code 63FCA06	Responsible Firm Manufacturer	PAC 56008A	Hours 5.5
Compliance Num	Country of Origin United States				
Related Smpl Num	Position Class INV	Sampling District ATL-DO	NDC Number 62794-145-10	Permit Number	Storage Rqmnt. Ambient
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name DIGITEK (digoxin tablets, USP) 125 mcg (0.125 mg)	
No					

Product Description

Digoxin Tablets, USP packed in a white plastic bottle w/white screw-on top, NDC 62794-145-10.

Product Label

See continuation.

Reason for Collection

Sample collected as part of the FY 2008 Low Cost Generic Drug Sample Survey (CP 7356.008) FACTS Assignment #896749 ORA concurrence #2008101702.

MFG Codes 70737A1	Expiration Date SEP 09
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Firm Legal Name (b)(4)	Address (b)(4)	Type of Firm Dealer	Firm FEI (b)(4)	FCE
UDL Laboratories, Inc	12720 Dairy Ashford Rd Sugar Land, TX 77478-2844 US	Manufacturer	1610608	
Actavis Totowa LLC	101 E Main St Little Falls, NJ 07424-5608 US	Manufacturer	2244683	
Size of Lot 12 bottles	Est. Value \$ (b)(4)	Rcpt Type FDA484	Carrier Name	Date Shipped

Description of Sample

Sample consists of 1 bottle of DIGITEK (digoxin tablets, USP) 125 mcg (0.125 mg) containing 1000 tablets. NDC 62794-145-10.

Method of Collection

The sample bottle was collected randomly from the warehouse line.

How Prepared

See continuation.

Collector's Identification on Package and/or Label
"453913 02/15/08 ARR"

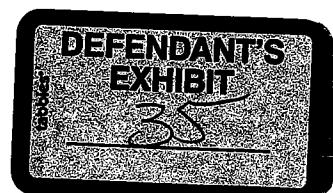
Collector's Identification on Seal
"453913 02/15/08 April R. Bowen"

Sample Delivered To
FedEx

Date Delivered 02/19/2008	Orig C/R & Records To NWJ-DO
Lab w/Split Sample 0	Lab NRL

Date: 03/01/2010

Page: 1 of 3



Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 453913

This is an accurate reproduction of the original electronic record as of 03/01/2010.

Document Number	Document Date	Document Type	Document Remarks	
Remarks See continuation.				
Payment Amount \$124.55	Payment Method Billed	704(d) Sample No	702(b) Portion No	Collector's Name April R Bowen
Name of Signer April R Bowen		Date & Time of Signature 02/19/2008 11:49 AM ET		Meaning Collector

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 453913

This is an accurate reproduction of the original electronic record as of 03/01/2010.

Continuation:

Product Label

The sample bottle is labeled in part: "NDC 62794-145-10 DIGITEK (digoxin tablets, USP) 125 mcg (0.125 mg) 1000 TABLETS Rx only Each tablet contains: Digoxin, USP***125 mcg (0.125 mg)***Distributed by: BERTEK PHARMACEUTICALS INC. Sugar Land, TX 77478 USA Manufactured by: AMIDE PHARMACEUTICAL, INC. 101 East Main Street Little Falls, NJ 07424 USA Control No.:70737A1 Exp. Date: SEP 09***".

How Prepared

The sample bottle is identified as: "453913 02/15/08 ARB", placed in a whirl-pak bag identified as "453913 02/15/08 ARB", and officially sealed "453913 02/15/08 April R. Bowen". FDA form 525 was attached to the bag. The sample was placed in a box to be delivered to NRL via FedEx on 02/19/08.

Remarks

The sample was collected on 02/15/08, officially sealed, and kept under the supervision of Investigator April R. Bowen, under lock and key, under ambient conditions until prepared for shipping on 02/19/08.

Food and Drug Administration Office of Regulatory Affairs**Summary Report****For Sample Number: 453913****TD Sample Number:****Import Sample Number**

This is an accurate reproduction of the original electronic record as of 06/10/2008

Sample Class: Normal Everyday Sample

Sample Origin: Domestic

Sample Basis: Surveillance

Home District:

Sample Type: Official

Collecting District: ATL-DO

Orig C/R and Records To: NWJ-DO

Collection PACs: 56008A

Product Name: Digoxin (Cardiotonic); Human - Rx/Single Ingredient; Prompt Release Tablets

Product Description: Digoxin Tablets, USP packed in a white plastic bottle w/white screw-on top, NDC 62794-145-10.

Collection Reason: Sample collected as part of the FY 2008 Low Cost Generic Drug Sample Survey (CP 7356.008) FACTS Assignment #896749 ORA concurrence #2008101702.

Lab: NRL

Split Num 0

Date Received: 02/20/2008

Date Out of Lab: 06/10/2008

District Conclusion:

District Conclusion
Made By:

District

Disposition Reason:

Disposition
Authorized By:Disposition
Authorized Date

Performing Org

PAC

LID

PAF

Compliance No

Lab Class-Description

Laboratory Status

NRL-DCB-G

56008A

DRT

I - In Compliance

Completed

Lab Conclusion

The sample meets USP specifications for Identification, Content Uniformity and Dissolution.

Lab Conclusion Date Lab Conclusion Made By

06/10/2008

Mathew, Samuel K

Date: 06/10/2008

Page: 1 of 1

10/10/08

FLAG Original

ANALYST WORKSHEET		1 PRODUCT DIGITEK (digoxin tablets, USP) 125 mcg (0.125 mg)			2. SAMPLE NUMBER 453913	
3. SEALS	<input checked="" type="checkbox"/> INTACT <input type="checkbox"/> NONE	4. DATE REC'D 2/27/08	5. RECEIVED FROM Howard Lynch	6. DISTRICT OF LABORATORY NRL		
7. DESCRIPTION OF SAMPLE						
One clear, plastic bag officially sealed, "453913 02/15/08 April R. Bowen Investigator", containing one product bottle identified "453913 02/15/08 ARB". An FDA 525 is attached to the sample.						
8. NET CONTENTS	<input type="checkbox"/> NOT APPLICABLE <input checked="" type="checkbox"/> NOT DETERMINED <input type="checkbox"/> UNITS EXAMINED	DECLARE/UNIT AMOUNT FOUND % OF DECLARED	1000 tablets	9. LABEL- ING	<input type="checkbox"/> ORIGINAL(S) SUBMITTED <input checked="" type="checkbox"/> 1 COPIES SUBMITTED <input type="checkbox"/> NONE	
10. SUMMARY OF ANALYSIS						
Container: Round, opaque, white, plastic bottle with a similar, screw-on cap. Safety-seal beneath cap is intact. Bottle is approximately 5.5 cm. in diameter and 11 cm. in height.						
Labeling: Commercially-printed, rectangular, paper, stick-on label. Commercially-printed product insert is inside bottle.						
Code: "Control No.: 70737A1" and "Exp. Date: SEP 09" printed on the bottle label.						
Product: Round, flat and bevel, solid, light-yellow tablet. Tablet is unmarked and unscored on one side. Opposite side is 1/2-scored with markings "B" and "145". Tablet is approximately 6.5 mm in diameter.						
Analysis: Identification, Dissolution, and Content Uniformity.						
Method: USP 30 - NF 25, p. 1943.						
Results: See general continuation sheet page 2.						
11. RESERVE SAMPLE						
Original plastic bag containing one open product bottle. Bag is officially sealed "453913 6/15/08 Valentino Fiorella Analyst". Bottle is additionally identified "VF 2/27/08" and contains approximately 888 tablets by weight. Sample returned to the sample custodian.						
12. a. ANALYST SIGNATURE (Broke Seal <input checked="" type="checkbox"/>) <i>Valentino Fiorella</i>			13. b. WORK-SHEET CHECK	a. BY <i>S. matthew</i> b. DATE <i>6/10/08</i>		
b.			14. DATE REPORTED <i>6/10/08</i>			c.

GENERAL CONTINUATION SHEET	PRODUCT	SAMPLE NO.
	Digoxin Tablets (0.125 mg)	453913
<u>RESULTS:</u>		
<u>Identification</u>		
<p>The retention time of the major peak in the chromatogram of the <i>sample preparation</i> corresponds to that in the chromatogram of the <i>standard preparation</i>. <i>Complies</i></p>		
<u>Content Uniformity</u>		
(See computer printout pages 6 - 7 for complete results)		
Range: <u>95.4</u> % to <u>100.1</u> %; Average (\bar{X}) : <u>97.1</u> %; RSD: <u>1.5</u> %; s: <u>1.43</u>		
Acceptance Value (AV) = <u>4.8</u> %		
(Limit: AV ≤ 15.0 % unless otherwise specified in the individual monograph)		
<u>Dissolution</u>		
(See least squares line fitting pages 11 - 12 for complete results)		
Range: <u>96.0</u> % to <u>109.7</u> % ; Avg.: <u>101.9</u> %		
(Limit: Each unit is NLT Q+5% (Q=80%) for 6 units tested (Stage 1))		
ANALYST(S) <i>Valentino Fiorella</i>	ANALYST NO. 113	PAGE 2 OF 12 PAGES

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.125 mg)	SAMPLE NO. 453913
ANALYST(S) <i>Valentino Scirella</i>	ANALYST NO. 113	PAGE <i>3 OF 12</i> PAGES
FORM FDA 431a (5/84)		

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.125 mg)	SAMPLE NO. 453913
ANALYST(S) <i>Valentino Fiorelli</i>	ANALYST NO. 113	PAGE 4 OF 12 PAGES

General Continuation Sheet	Product: Digoxin Tablets (0.125 mg)	Sample No. 453913										
Statistical Analysis of Data: Standard Solution 1 (CCV) 03/03/2008												
<table><tr><td>Relative STD Deviation</td><td>0.23 %</td></tr><tr><td>Standard Deviation</td><td>1566.69471</td></tr><tr><td>Average (mean)</td><td>678866.6</td></tr><tr><td>Number of entries</td><td>5</td></tr><tr><td>Range</td><td>677216 To 681220</td></tr></table>			Relative STD Deviation	0.23 %	Standard Deviation	1566.69471	Average (mean)	678866.6	Number of entries	5	Range	677216 To 681220
Relative STD Deviation	0.23 %											
Standard Deviation	1566.69471											
Average (mean)	678866.6											
Number of entries	5											
Range	677216 To 681220											
Data Entered: 677721✓ 678819✓ 679357✓ 681220✓ 677216✓												
Analyst(s) <i>Valentino Fiorella</i>	Analyst No. 113	Page 5 of 12 Pages										

General Continuation Sheet	Product: Digoxin Tablets (0.125 mg)	Sample No. 453913
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Content Uniformity

03/04/2008

No. of Units Examined	10
Standard Weight	2.424 mg.
Standard Dilution	200
Sample Dilution	10

Data Entered:

Unit #1	673009	STD #1	678867
Unit #2	678988	Blank	0
Unit #3	668085		
Unit #4	679994		
Unit #5	673742		
Unit #6	692885		
Unit #7	682775		
Unit #8	676772		
Unit #9	673296		
Unit #10	700860		

CONTENT UNIFORMITY RESULTS:

	FOUND (mg/tablet)	DECLARED	% of DECLARED
UNIT #1	0.120	0.125	96.1
UNIT #2	0.121	mg/tablet	97.0
UNIT #3	0.119		95.4
UNIT #4	0.121		97.1
UNIT #5	0.120		96.2
UNIT #6	0.124		99.0
UNIT #7	0.122		97.5
UNIT #8	0.121—		96.7
UNIT #9	0.120		96.2
UNIT #10	0.125		100.1
Avg.	0.121		97.1

OFFICIAL LIMITS:	90.0 % TO 105.0 %
No. of Units Examined	10
RANGE	95.4 % TO 100.1 % of Declared
UNITS >=85 BUT <=115 % of Avg. Limit	10
UNITS >=75 BUT <85 OR >115 BUT <=125 % of Avg. Limit	0
UNITS <75 OR >125 % of Avg. Limit	0
REL. STD. DEV. :	1.5 LIMIT <= 6.0%

$$\text{mg/unit} = (R_{\text{spl}} * \text{std_wt} * \text{spl_dil}) / (R_{\text{std}} * \text{std_dil} * 1 \text{ unit})$$

Analyst(s) <i>Valentino Fiorella</i>	Analyst No. 113	Page 6 of 12 Pages
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General Continuation Sheet	Product: Digoxin Tablets (0.125 mg)	Sample No. 453913
Statistical Analysis of Data:		Content Uniformity Standard Deviation
Relative STD Deviation		1.47 %
Standard Deviation		1.43
Average (mean)		97.13
Number of entries		10
Range		95.4 To 100.1
Data Entered:		
96.1 97. 95.4 97.1 96.2 99 97.5 96.7 96.2 100.1		
Analyst(s) <i>Valentino Ferrell</i>	Analyst No. 113	Page 7 of 12 Pages

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.125 mg)	SAMPLE NO. 453913
ANALYST(S) <i>Valentino Ficelli</i>	ANALYST NO. 113	PAGE <i>8</i> OF <i>12</i> PAGES
FORM FDA 431a (5/84)		

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.125 mg)	SAMPLE NO. 453913
ANALYST(S) <i>Valentino Firicella</i>	ANALYST NO 113	PAGE 9 OF 12 PAGES

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.125 mg)	SAMPLE NO. 453913
ANALYST(S) <i>Valentino Fiorella</i>	ANALYST NO. 113	PAGE 10 OF 12 PAGES
FORM FDA 431a (5/84)		

General Continuation Sheet	Product: Digoxin Tablets (0.125 mg)	Sample No. 453913
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Least Squares Line Fitting

06/05/2008

The Line Fitting used is $Y = mX + b$ —

with $m = 0.021965$
 and $b = -0.0801$
 Correlation Coefficient = 0.99976175

Data Entered:

	X	y	LSLF y	% Deviation
20% Std.	20	0.37	0.3592	3.007
40% Std.	40	0.774	0.7985	3.068
60% Std.	60	1.25	1.2378	0.986
80% Std.	80	1.683	1.6771	0.352
100% Std.	100	2.112	2.1164	0.208

Extrapolated Data:

	X	AVG	Y
Tablet 1-Test 1	112.55		2.392
Tablet 1-Test 2	106.81	109.68	2.266
Tablet 2-Test 1	98.66		2.087
Tablet 2-Test 2	99.07	98.87	2.096
Tablet 3-Test 1	102.26		2.166
Tablet 3-Test 2	105.35	103.81	2.234

Analyst(s) <i>Valentino Firell</i>	Analyst No. 113	Page 11 of 12 Pages
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General Continuation Sheet	Product: Digoxin Tablets (0.125 mg)	Sample No. 453913
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Least Squares Line Fitting

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40% Std.	40	0.774	0.7985	3.068
60% Std.	60	1.25	1.2378	0.986
80% Std.	80	1.683	1.6771	0.352
100% Std.	100	2.112	2.1164	0.208

Extrapolated Data:

	X	AVG	Y
Tablet 4-Test 1	96.70		2.044
Tablet 4-Test 2	100.62	98.66	2.130
Tablet 5-Test 1	103.21		2.187
Tablet 5-Test 2	105.67	104.44	2.241
Tablet 6-Test 1	93.84		1.981
Tablet 6-Test 2	98.07	95.95	2.074

Analyst(s) <i>Valentino Fiorelli</i>	Analyst No. 113	Page 12 of 12 Pages
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ATTACHMENT A - Page 1 of 20 pages

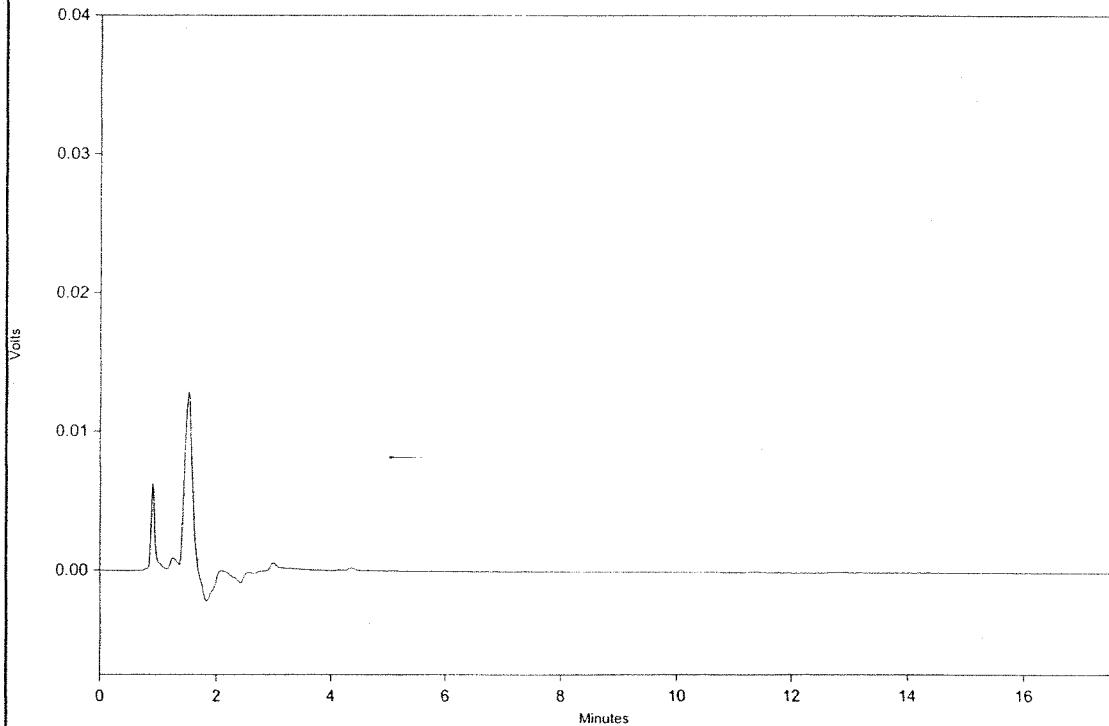
Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Blank
 Method: C:\CLASS-VP\METHODS\DigoxinTabs.met
 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Blank-Rep2
 Date: 03/03/2008 9:38:32 AM
 Vial: 0
 Injection Volume: 50 μ l

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

ATTACHMENT A - Page 2 of 20 pages

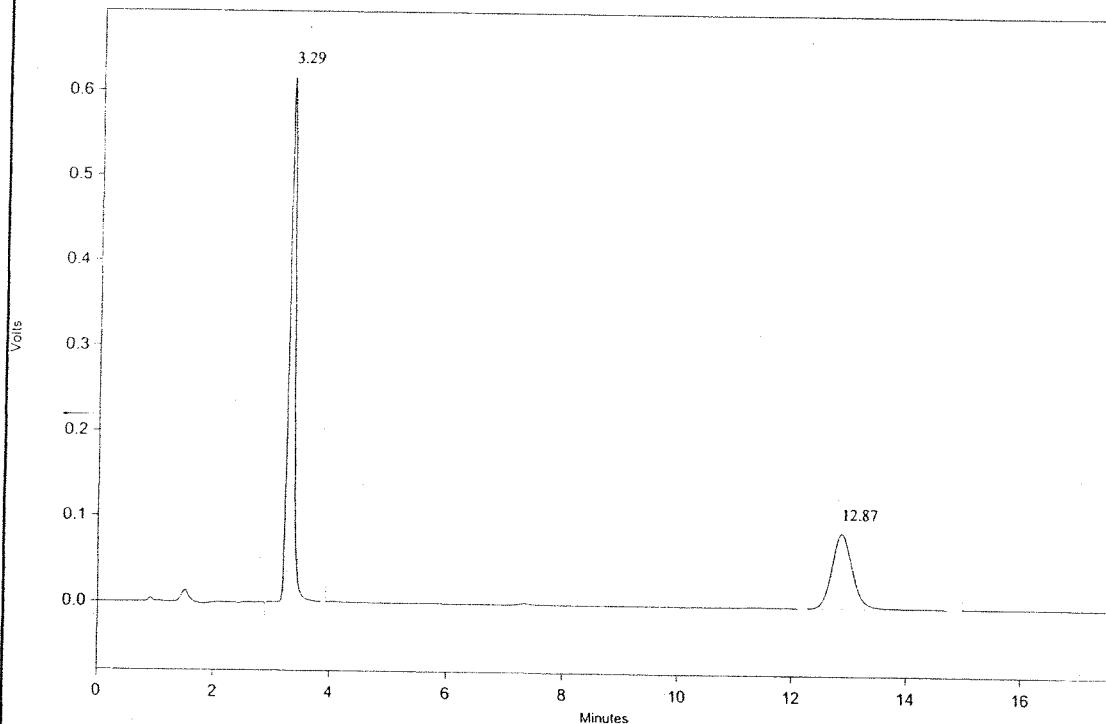
Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: System Suitability Solution
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 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\SysSuitSoln
 Date: 03/03/2008 9:57:33 AM
 Vial: 1
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxigenin	3.29	4318725	616256	1.2	0.0	3452
2	Digoxin	12.87	2169893	87343	1.2	22.0	6364
Totals			6488618	703599			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 3 of 20 pages

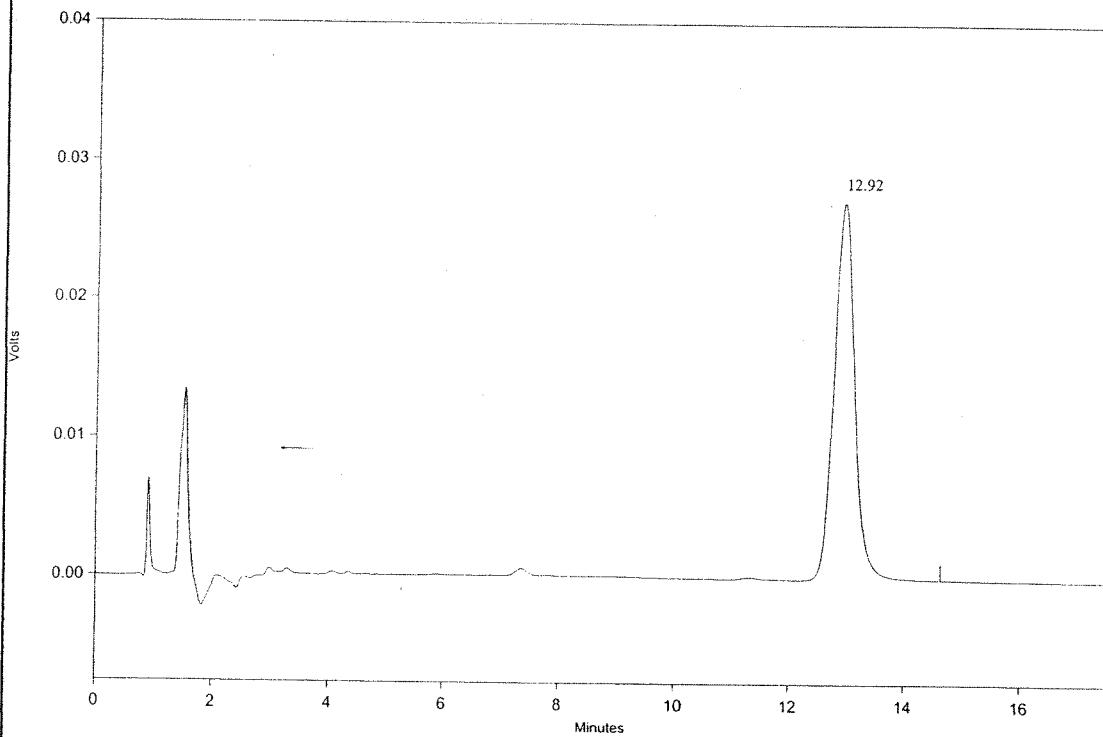
Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Standard Solution 1 (CCV)
 Method: C:\CLASS-VP\METHODS\DigoxinTabs.met
 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Std.Soln-Rep1.
 Date: 03/03/2008 10:16:33 AM
 Vial: 2
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	12.92	677721	27189	1.2	0.0	6358
Totals			677721	27189			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 4 of 20 pages

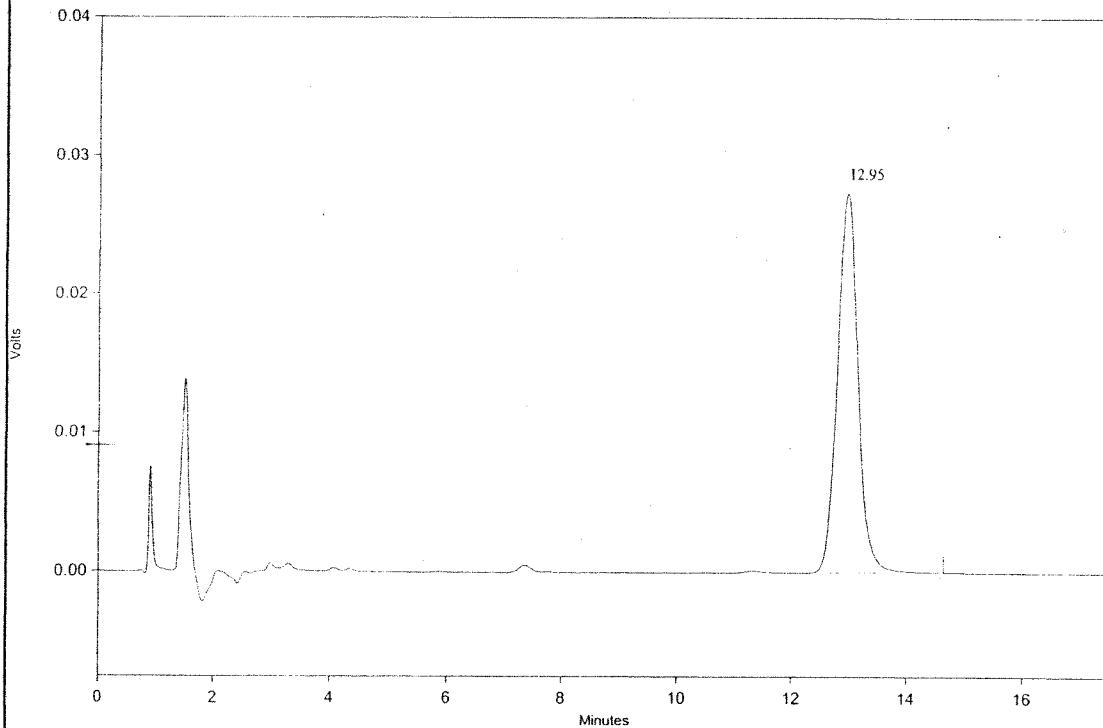
Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Standard Solution 1 (CCV)
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 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Std.Soln-Rep2.
 Date: 03/03/2008 10:35:32 AM
 Vial: 2
 Injection Volume: 50 uL

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	12.95	678819	27370	1.1	0.0	6417
Totals			678819	27370			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (*QA by V.Fiorella on 1/3/08*)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 5 of 20 pages

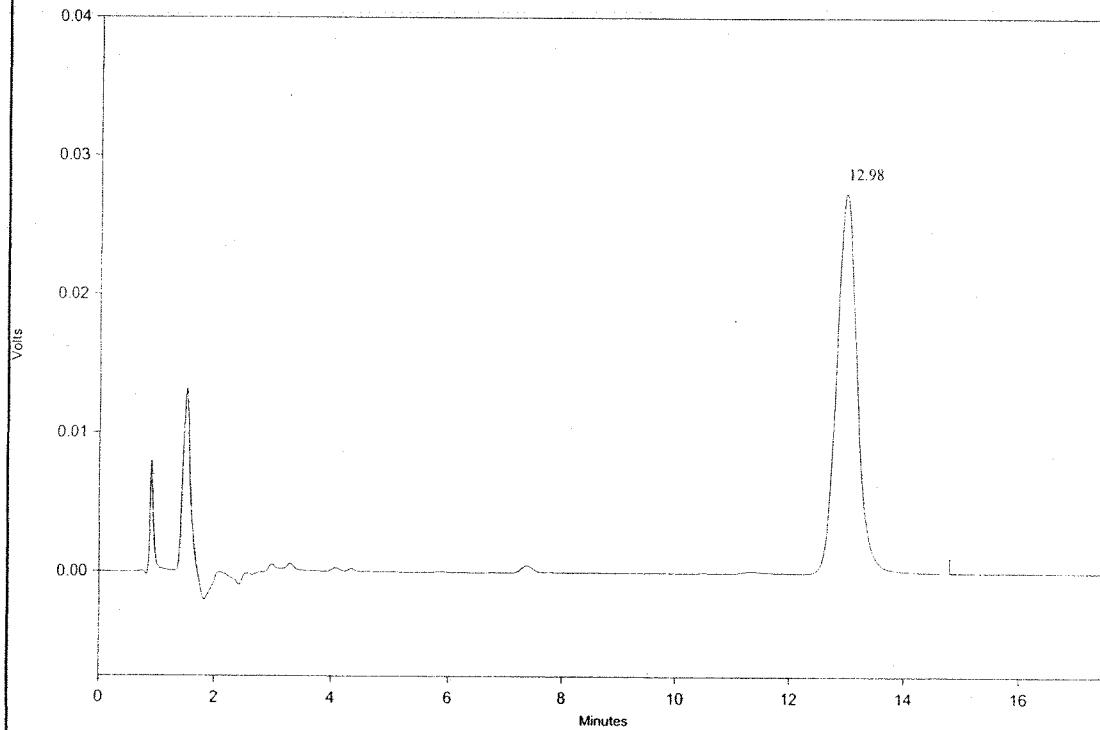
Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Standard Solution 1 (CCV)
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 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Std.Soln-Rep3.
 Date: 03/03/2008 10:54:30 AM
 Vial: 2
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	12.98	679357	27392	1.1	0.0	6424
Totals			679357	27392			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (*QA by V.Fiorella on 1/3/08*)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

ATTACHMENT A - Page 6 of 20 pages

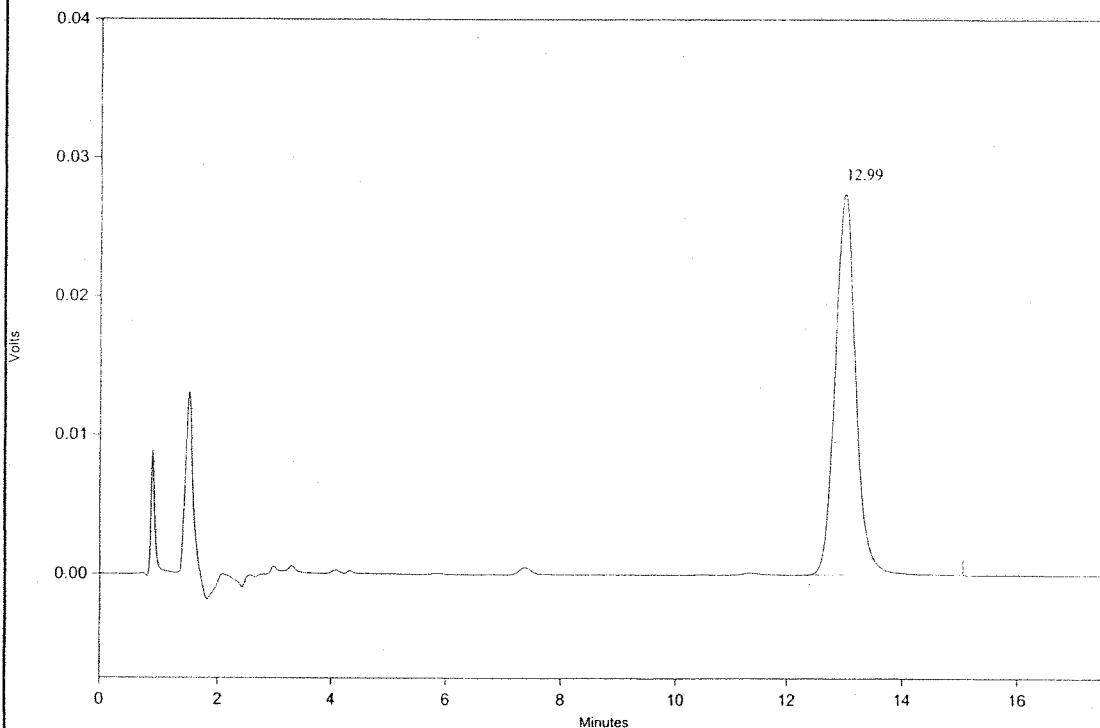
Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Standard Solution 1 (CCV)
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 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Std.Soln-Rep4.
 Date: 03/03/2008 11:13:28 AM
 Vial: 2
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	12.99	681220	27435	1.1	0.0	6372
Totals			681220	27435			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

ATTACHMENT A - Page 7 of 20 pages

Product: Digoxin Tablets (0.125 mg)

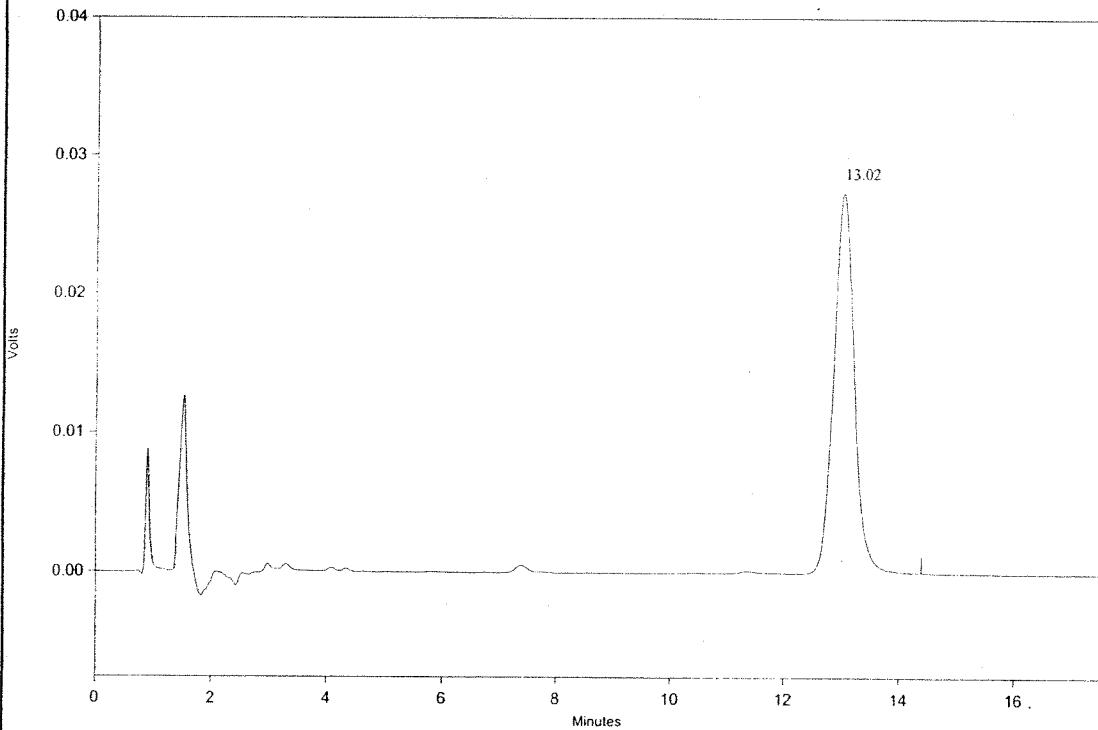
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Name: Standard Solution 1 (CCV)
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 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Std.Soln-Rep5.
 Date: 03/03/2008 11:32:22 AM
 Vial: 2
 Injection Volume: 50 ul

Detector A

(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.02	677216	27387	1.1	0.0	6487
Totals			677216	27387			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 8 of 20 pages

Product: Digoxin Tablets (0.125 mg)

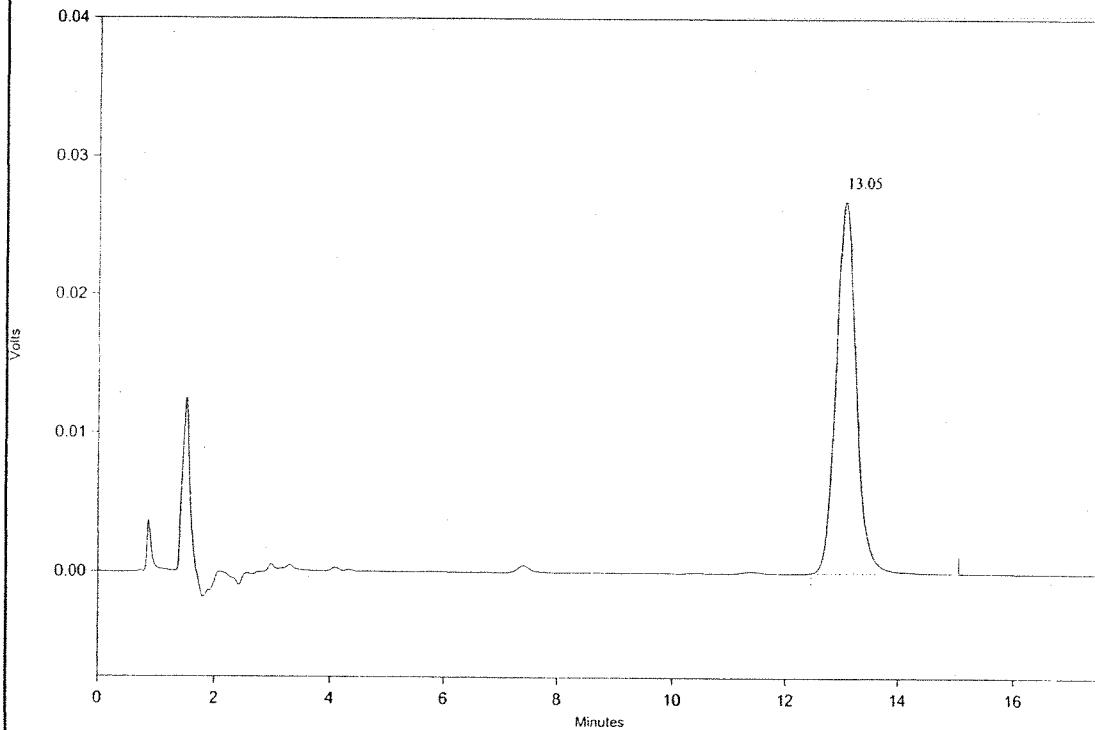
Spl.No. 453913

Name: Standard Solution 2 (ICV)
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 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\CheckStd.
 Date: 03/03/2008 11:51:20 AM
 Vial: 3
 Injection Volume: 50 ul

Detector A

(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.05	671200	26815		1.1	0.0
Totals			671200	26815			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 9 of 20 pages

Product: Digoxin Tablets (0.125 mg)

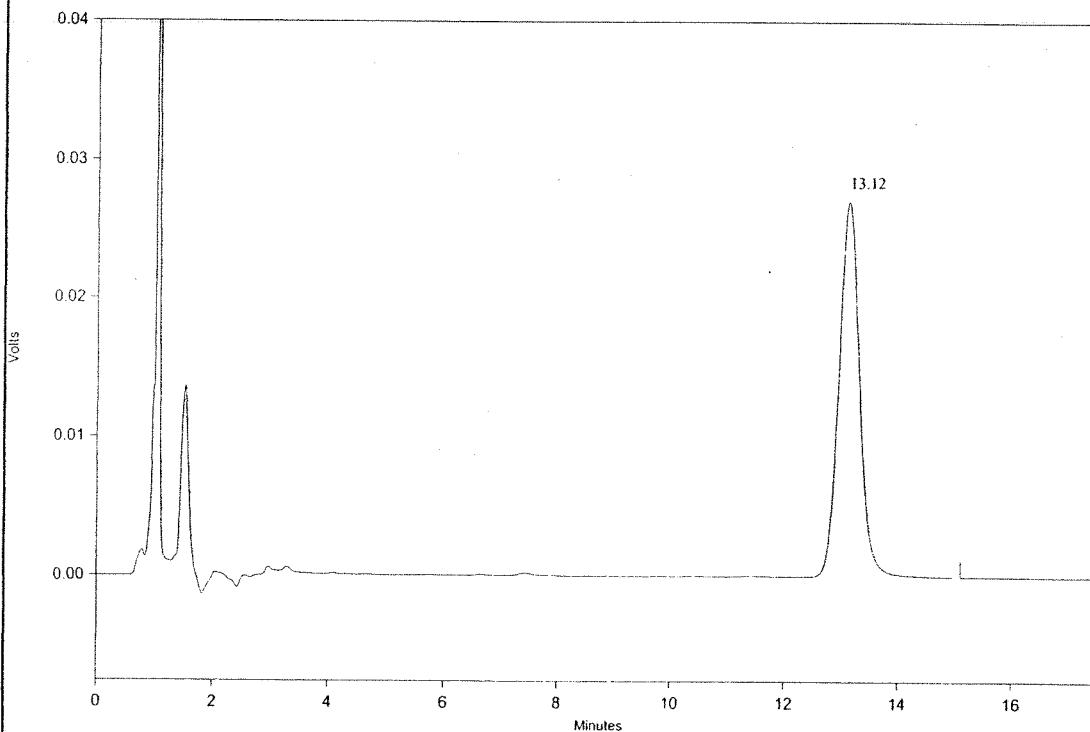
Spl.No. 453913

Name: Tablet I
 Method: C:\CLASS-VP\METHODS\DigoxinTabs.met
 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab1
 Date: 03/03/2008 12:10:18 PM
 Vial: 4
 Injection Volume: 50 ul

Detector A

(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.12	673009	27049	1.1	0.0	6611
Totals			673009	27049			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

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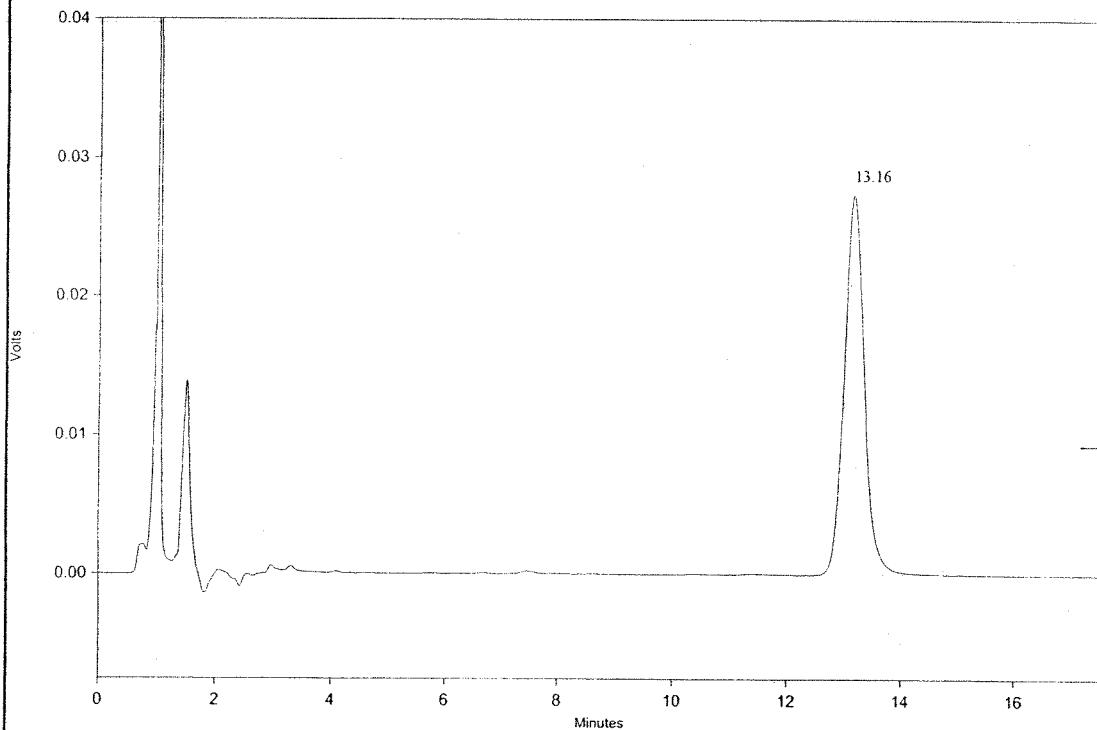
Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 2
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 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab2
 Date: 03/03/2008 12:29:17 PM
 Vial: 5
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.16	678988	27390	1.1	0.0	6543
Totals			678988	27390			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

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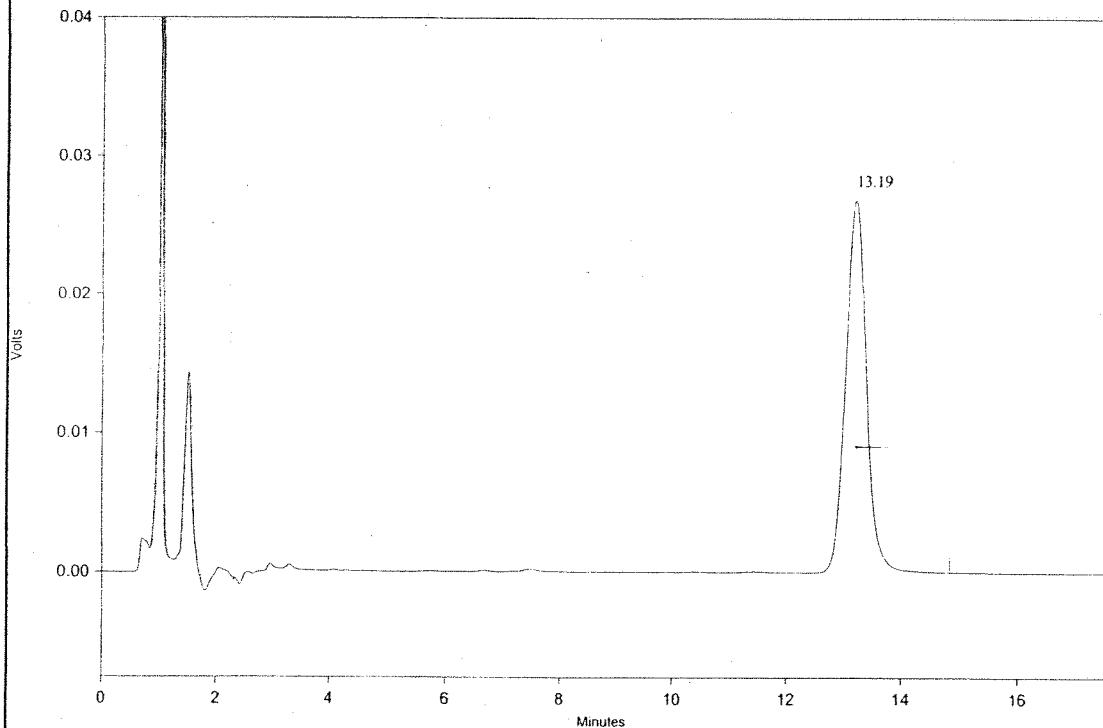
Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 3
 Method: C:\CLASS-VP\METHODS\DigoxinTabs.met
 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab3
 Date: 03/03/2008 12:48:15 PM
 Vial: 6
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.19	668085	26856		1.1	0.0
Totals			668085	26856			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (*QA by V.Fiorella on 1/3/08*)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 mL/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

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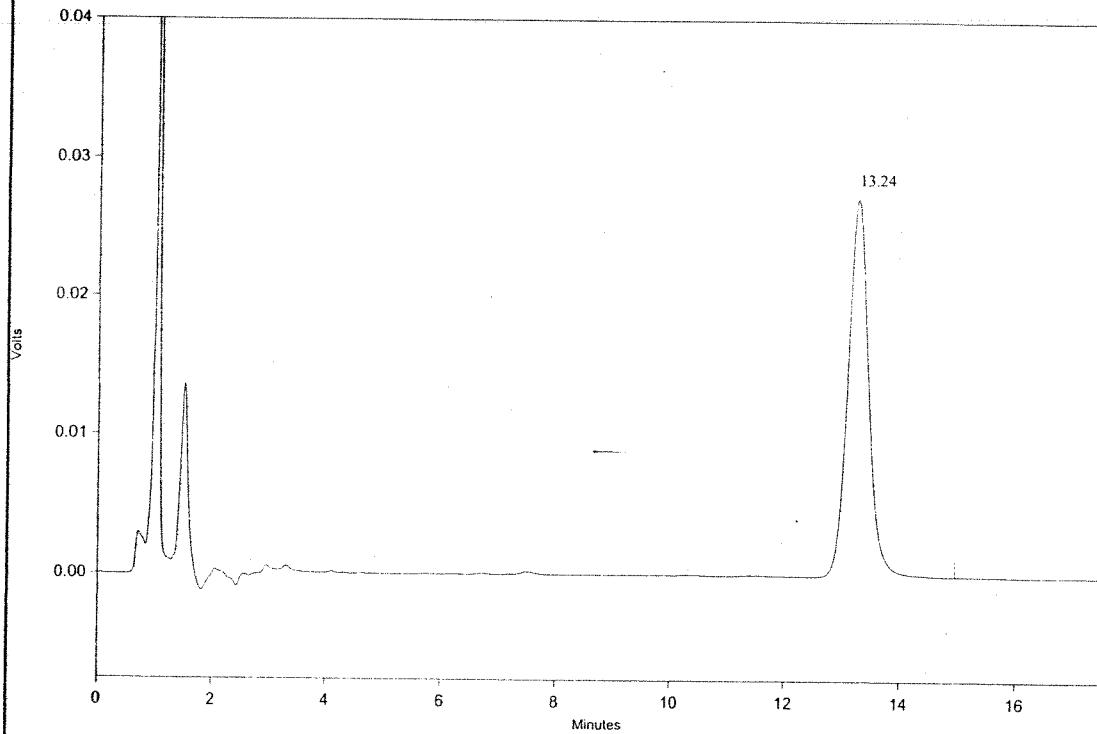
Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 4
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 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab4
 Date: 03/03/2008 1:07:13 PM
 Vial: 7
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.24	679994	27235	1.1	0.0	6612
Totals			679994	27235			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (*QA by V.Fiorella on 1/3/08*)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 mL/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

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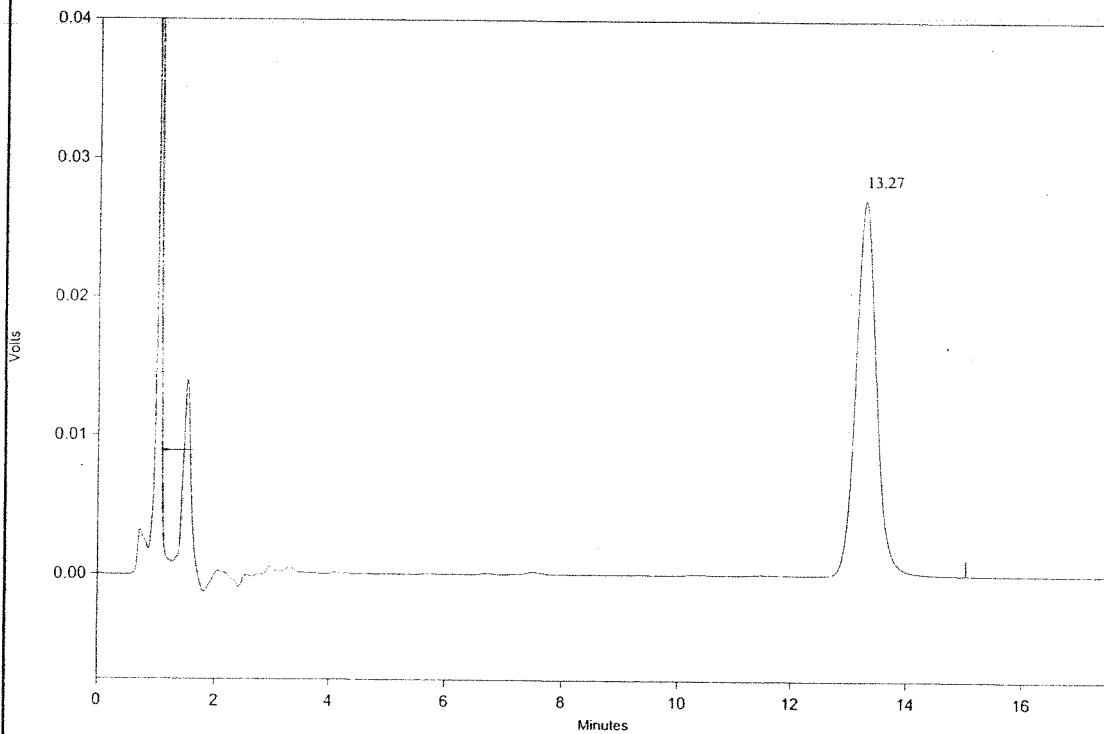
Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 5
 Method: C:\CLASS-VP\METHODS\DigoxinTabs.met
 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab5
 Date: 03/03/2008 1:26:11 PM
 Vial: 8
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.27	673742	27036	1.1	0.0	6649
Totals			673742	27036			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (*QA by V.Fiorella on 1/3/08*)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

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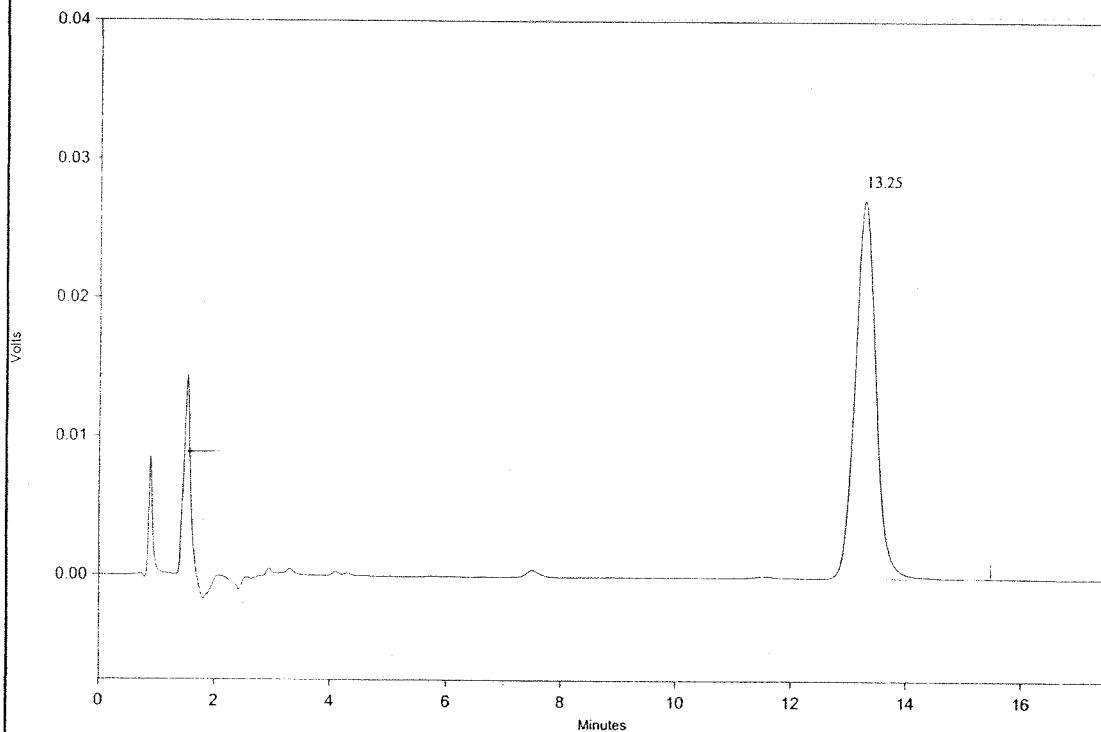
Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Standard Solution 1 (CCV)
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 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Std.Soln.6
 Date: 03/03/2008 1:45:09 PM
 Vial: 2
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.25	678890	27219	1.1	0.0	6646
Totals			678890	27219			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (*QA by V.Fiorella on 1/3/08*)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

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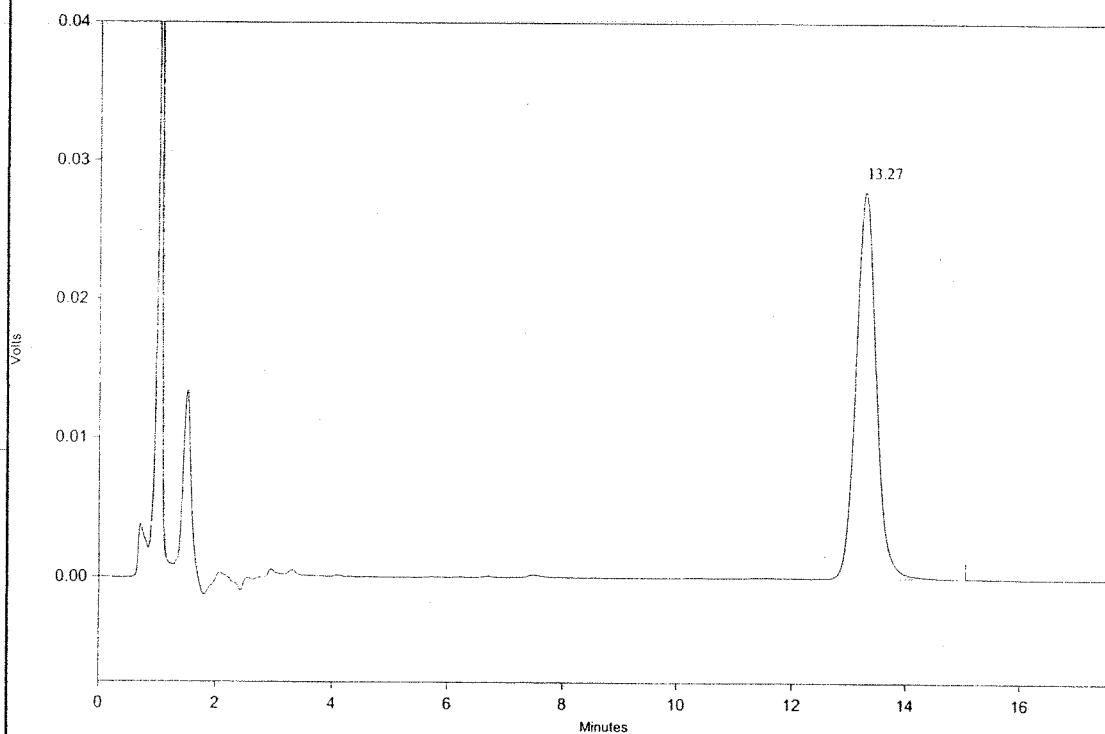
Product: Digoxin Tablets (0.125 mg)

SPL.No. 453913

Name: Tablet 6
 Method: C:\CLASS-VP\METHODS\DigoxinTabs.met
 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab6
 Date: 03/03/2008 2:04:08 PM
 Vial: 9
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.27	692885	27805	1.1	0.0	6622
Totals			692885	27805			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

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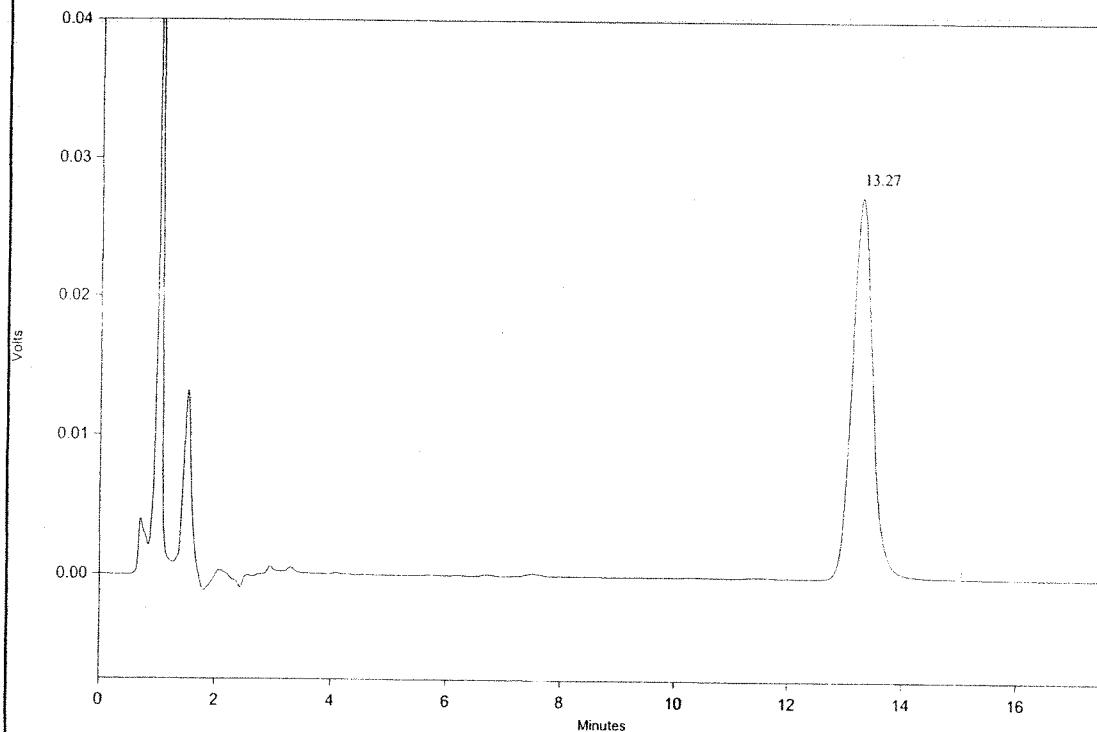
Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 7
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 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab7
 Date: 03/03/2008 2:23:07 PM
 Vial: 10
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.27	682775	27431	1.1	0.0	6625
Totals			682775	27431			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (*QA by V.Fiorella on 1/3/08*)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

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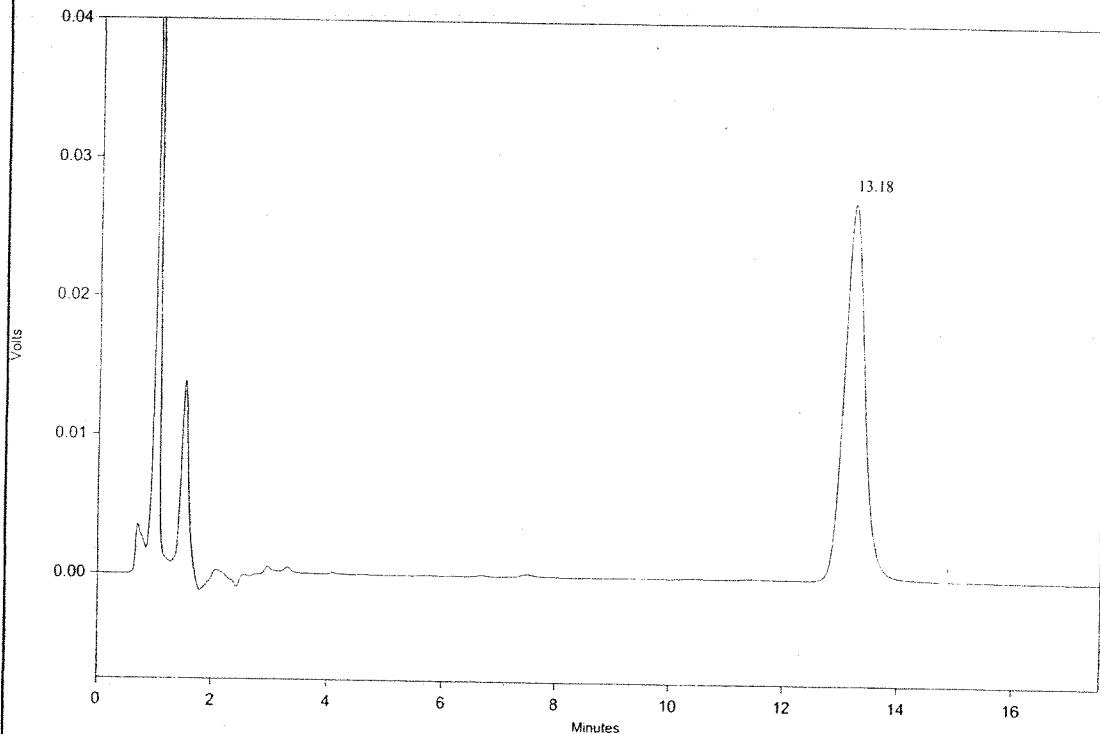
Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 8
 Method: C:\CLASS-VP\METHODS\DigoxinTabs.met
 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab8
 Date: 03/03/2008 2:42:07 PM
 Vial: 11
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.18	676772	27151	1.1	0.0	6650
Totals			676772	27151			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

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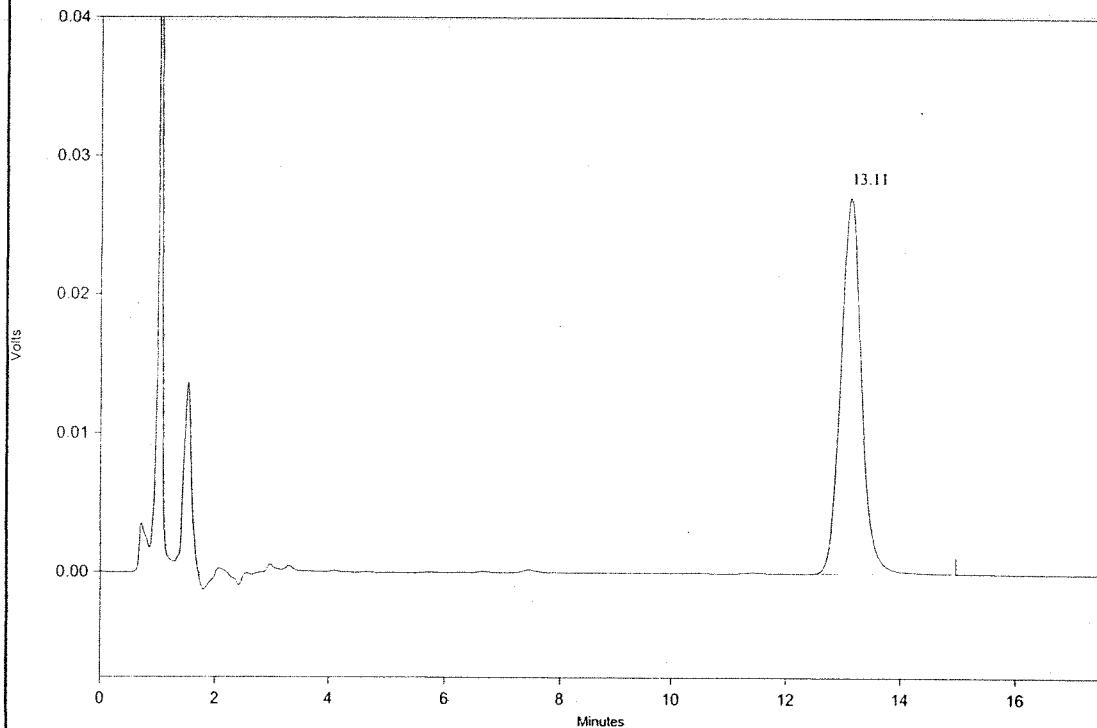
Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 9
 Method: C:\CLASS-VP\METHODS\DigoxinTabs.met
 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab9
 Date: 03/03/2008 3:01:05 PM
 Vial: 12
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.11	673296	27081		1.1	0.0
Totals			673296	27081			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

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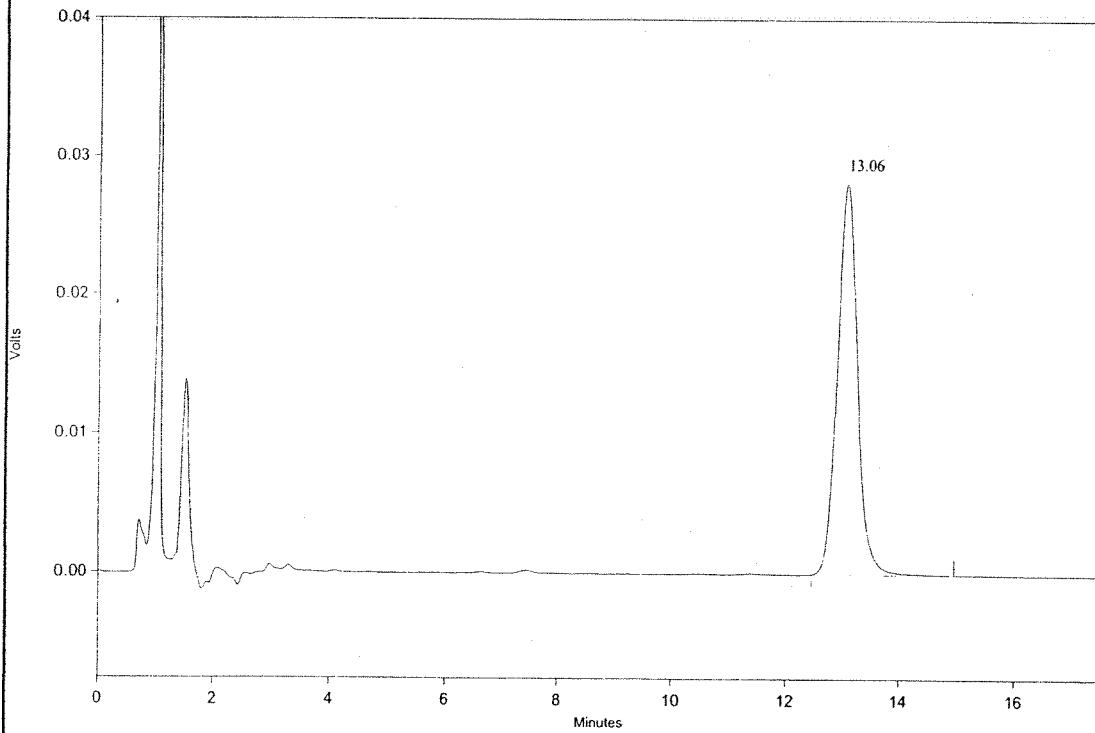
Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 10
 Method: C:\CLASS-VP\METHODS\DigoxinTabs.met
 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab10
 Date: 03/03/2008 3:20:04 PM
 Vial: 13
 Injection Volume: 50 μ l

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.06	700860	28158	1.1	0.0	6593
Totals			700860	28158			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (*QA by V.Fiorella on 1/3/08*)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

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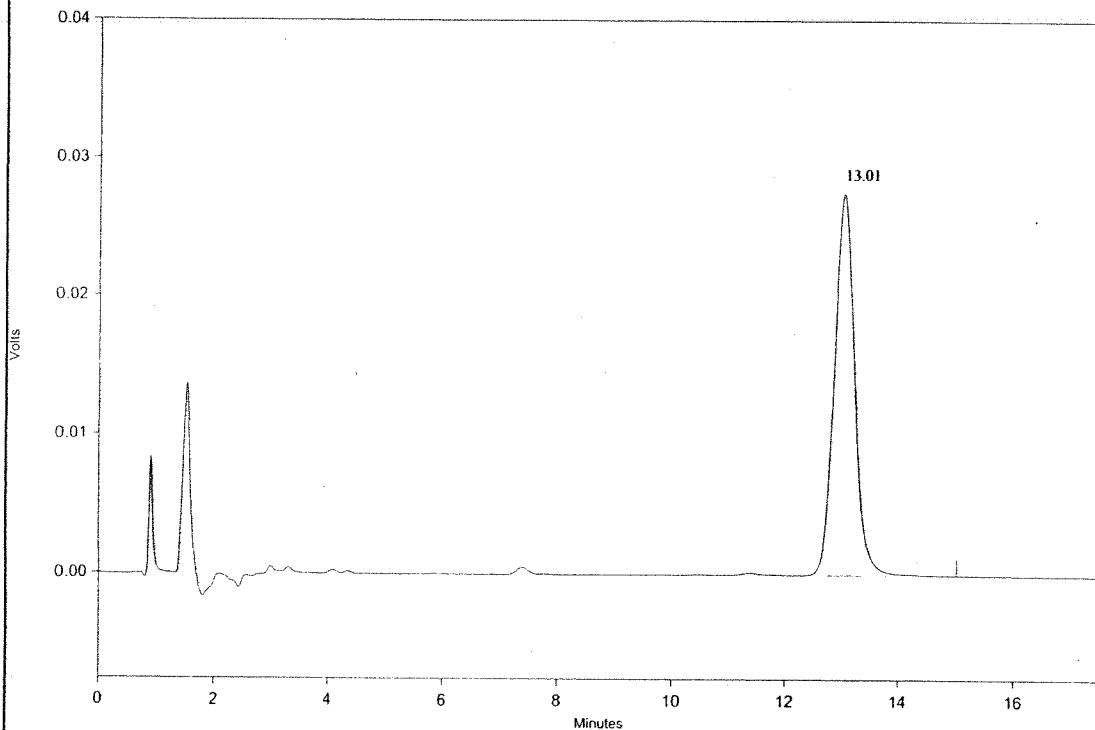
Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

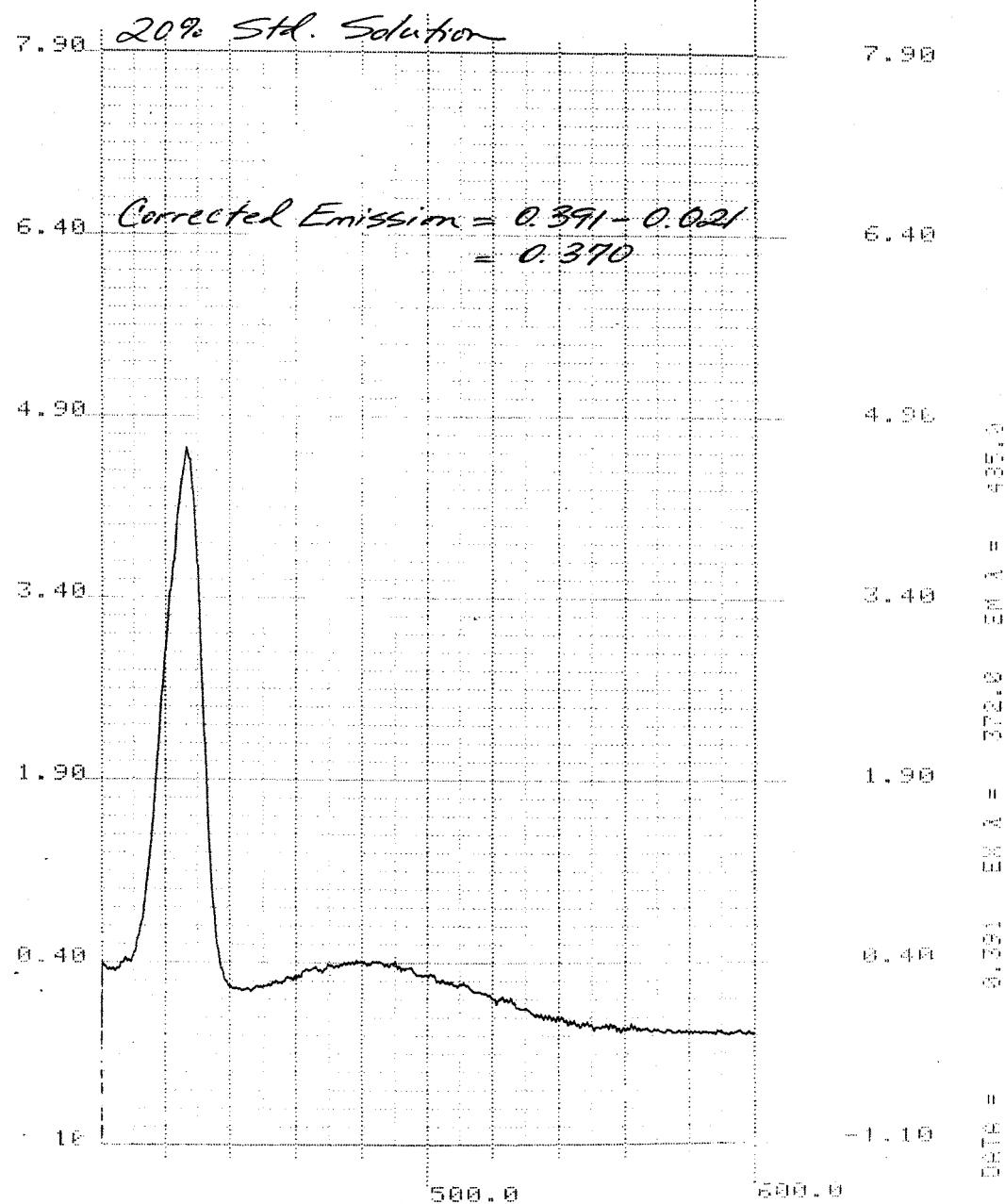
Name: Standard Solution 1 (CCV)
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 File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Std.Soln.7
 Date: 03/03/2008 3:38:59 PM
 Vial: 2
 Injection Volume: 50 uL

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.01	680967	27510	1.1	0.0	6483
Totals			680967	27510			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (*QA by V.Fiorella on 1/3/08*)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 mL/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μm), Serial No. 88682C



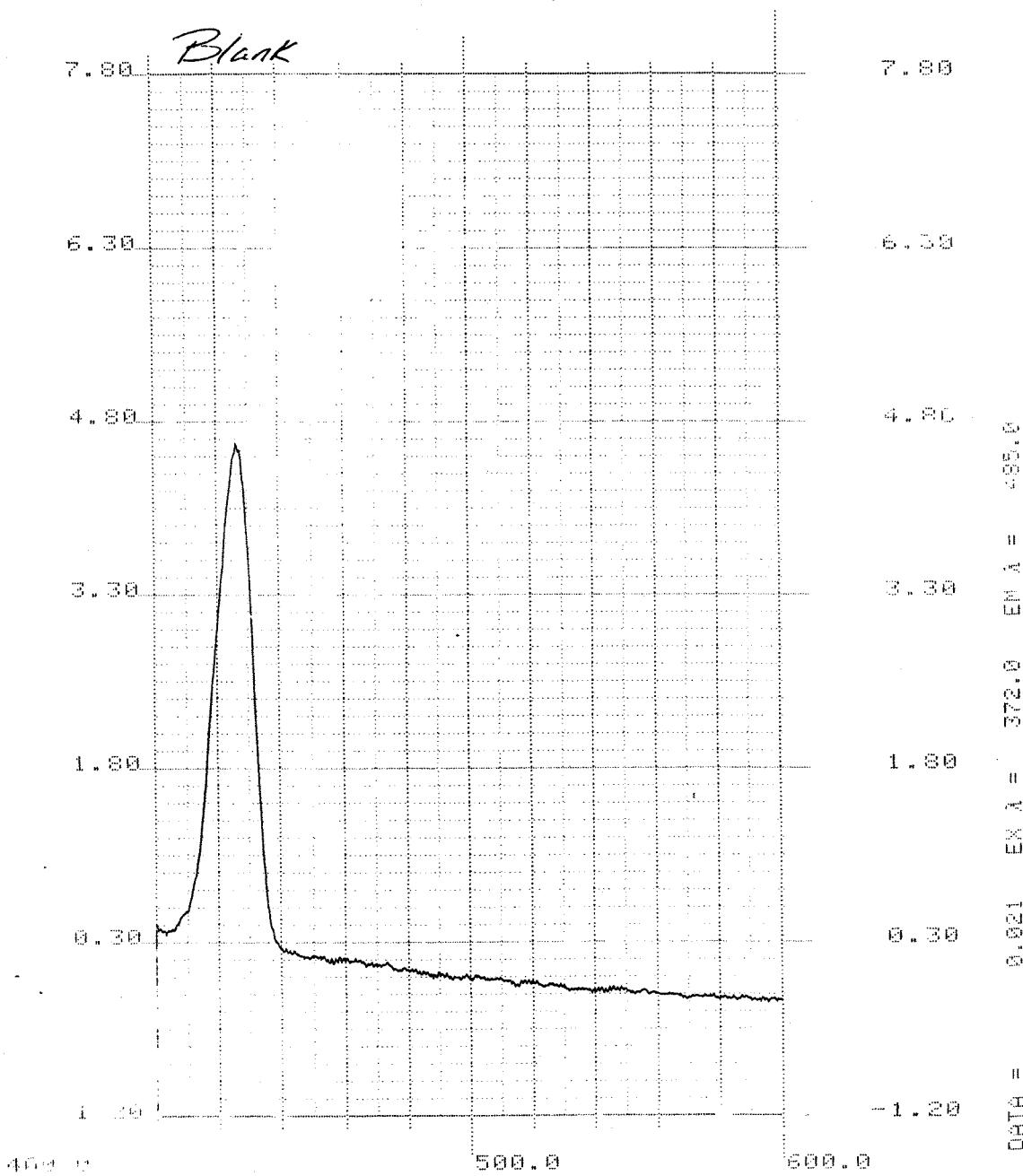
Attachment B

Digoxin Tablets (0.125 mg)

Spl.# 453913

6/4/08

*Attachment B
Digoxin Tablets (0.125mg)
Spl. #453913
6/4/08 VF*

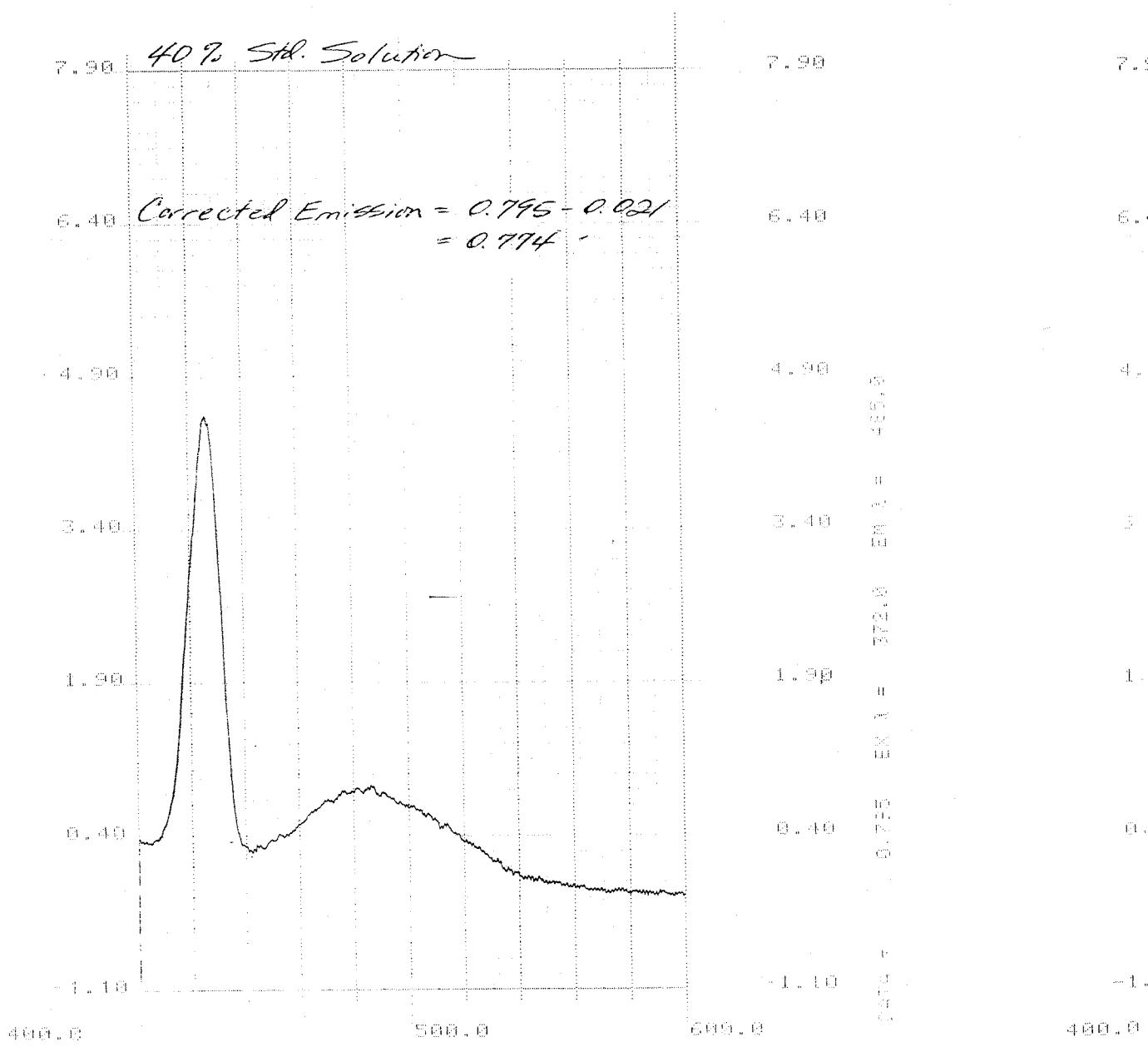


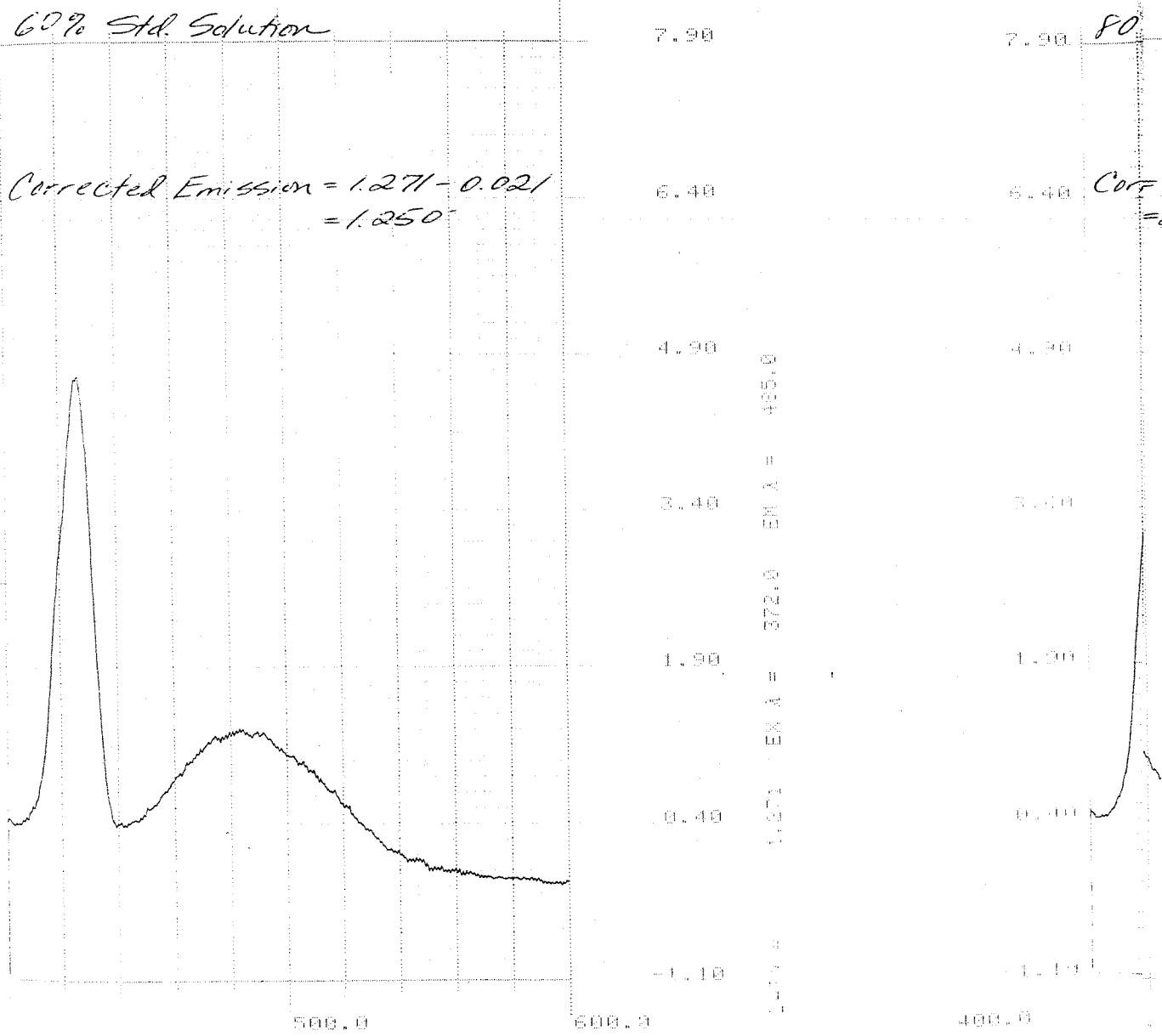
Attachment B

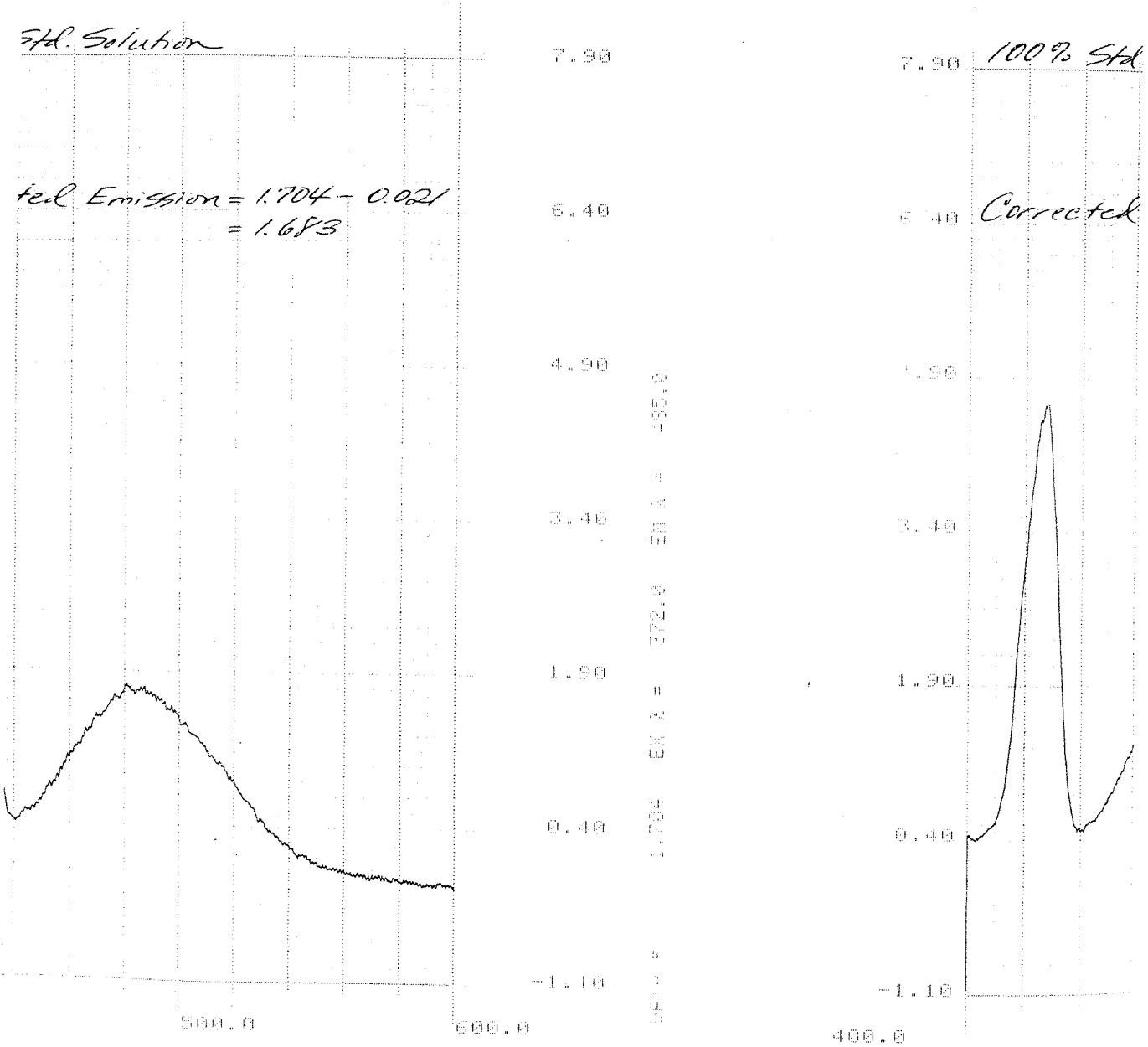
Digoxin Tablets (0.125 mg)

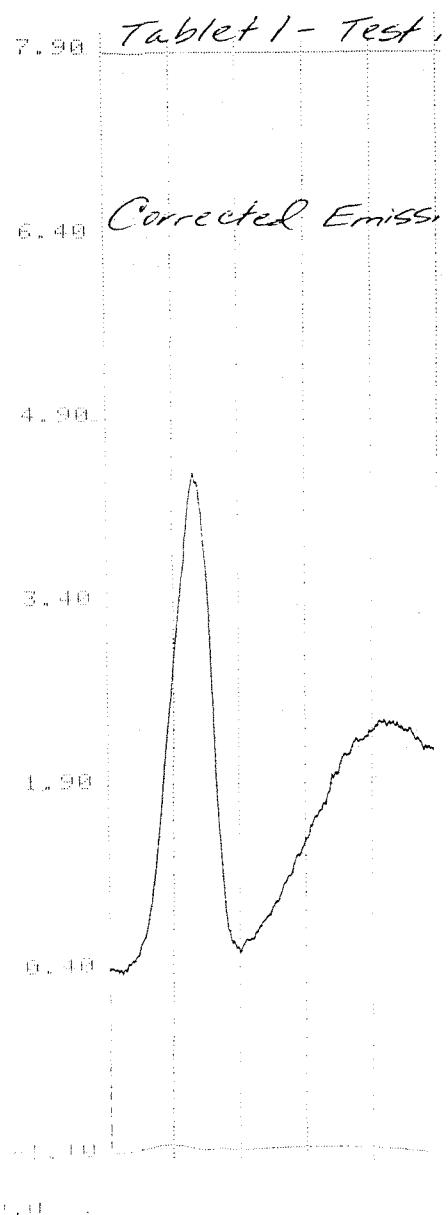
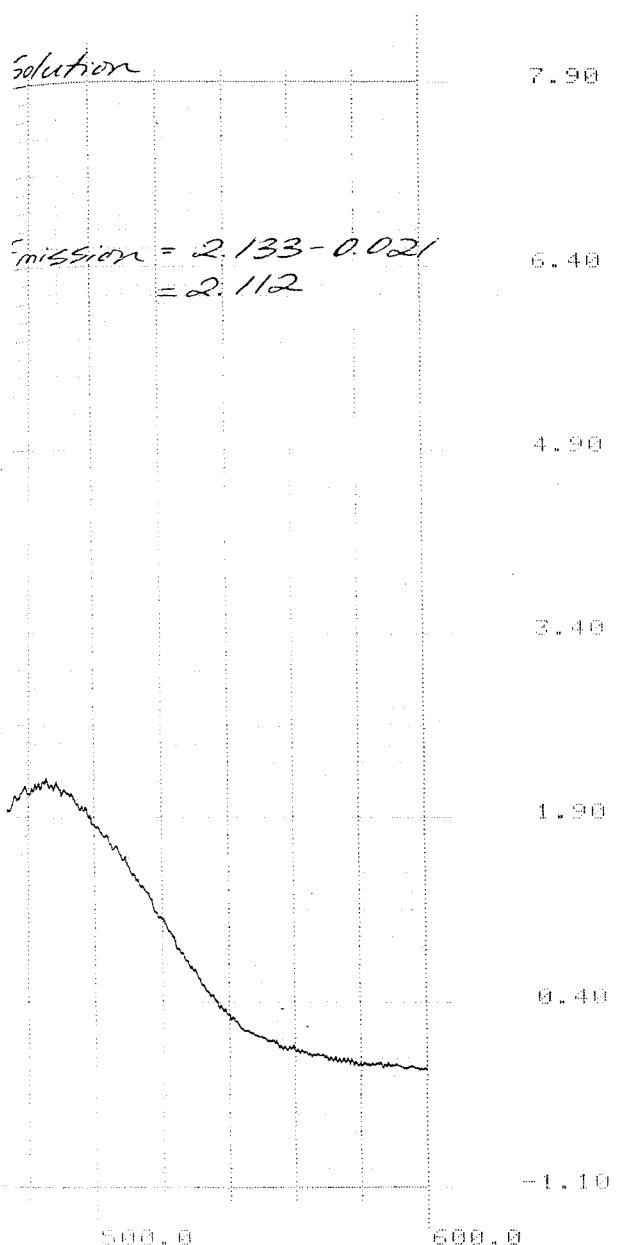
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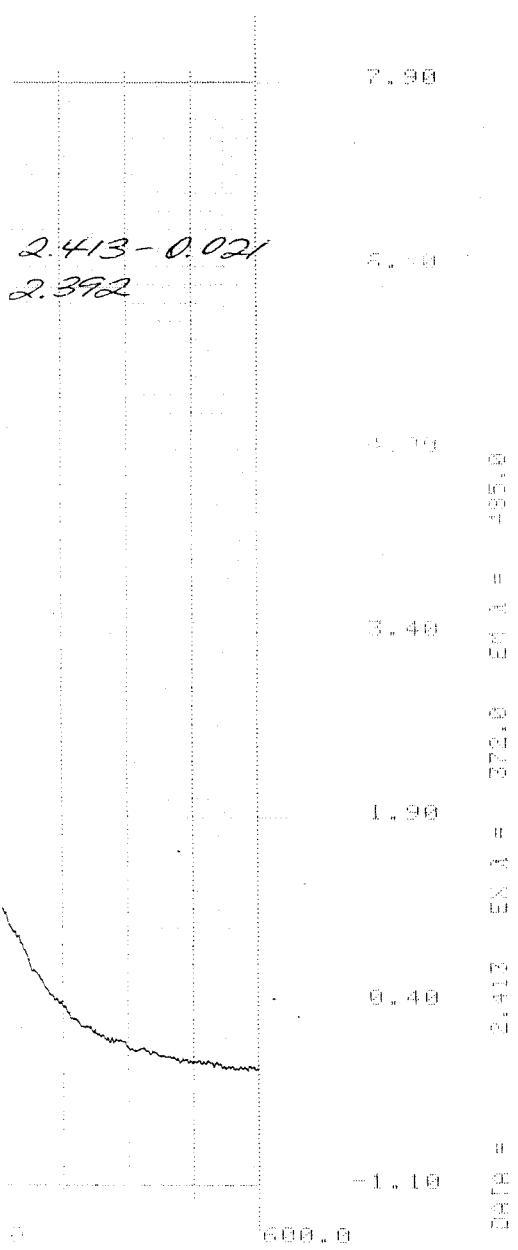
6/4/08



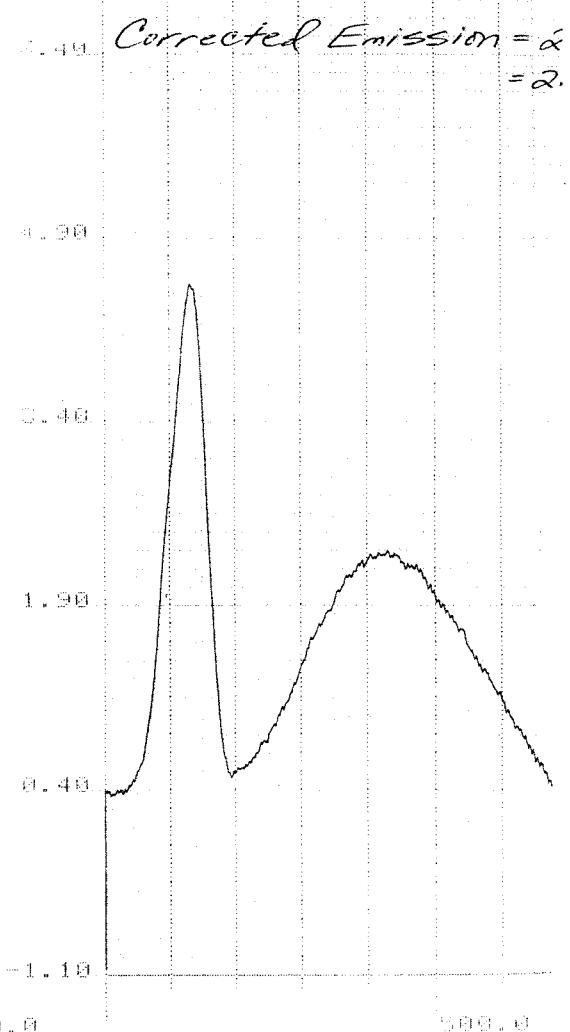


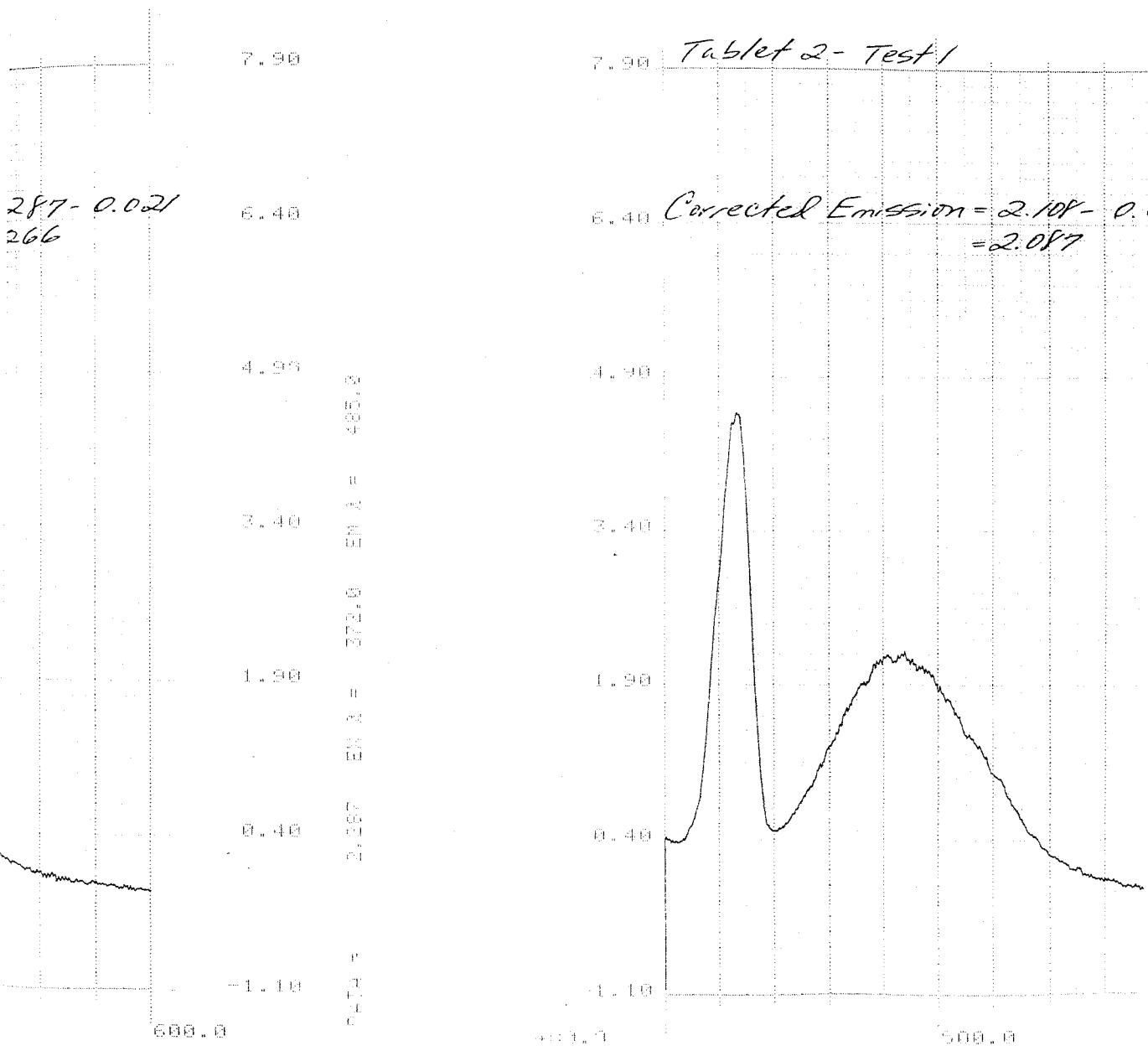


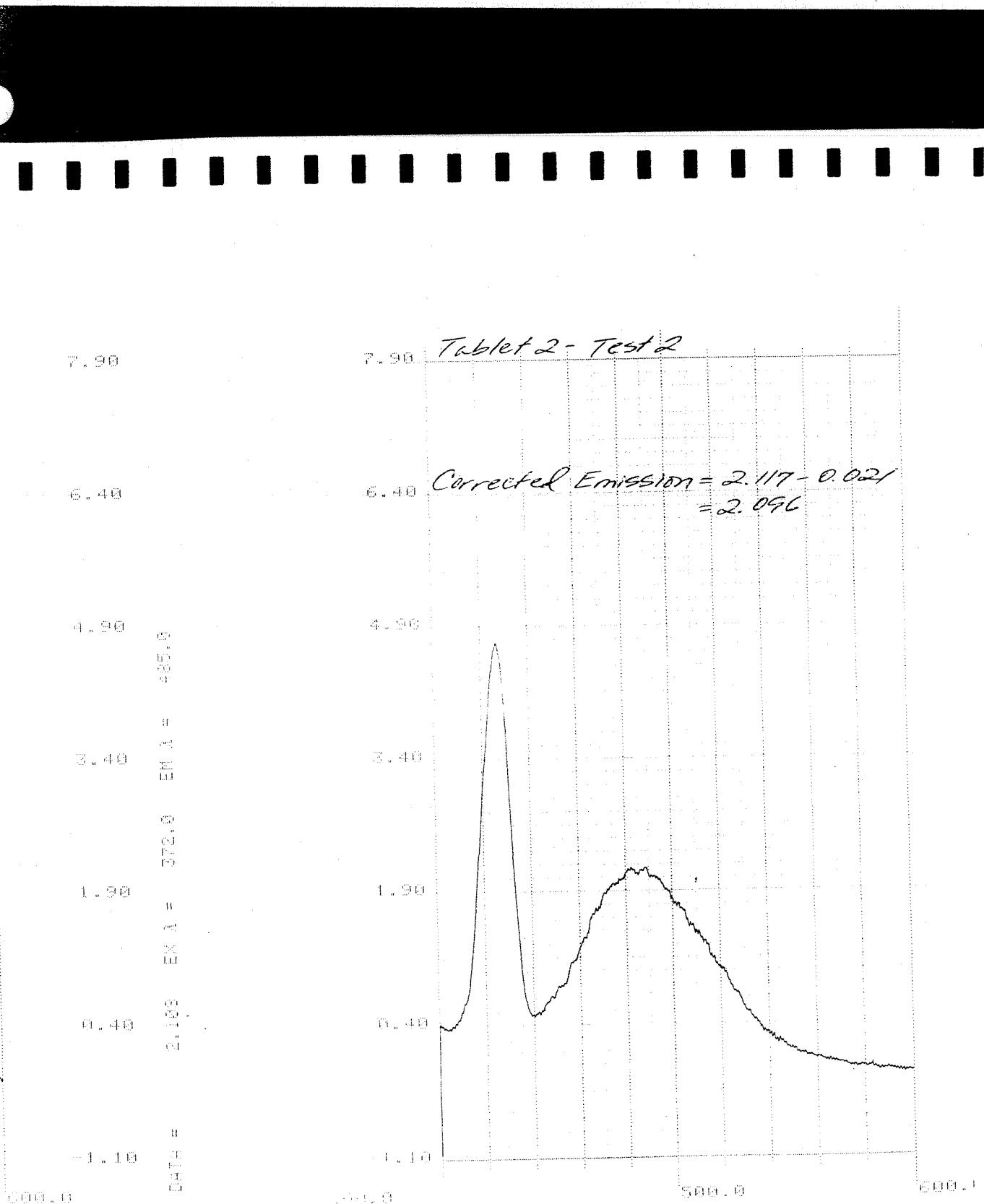


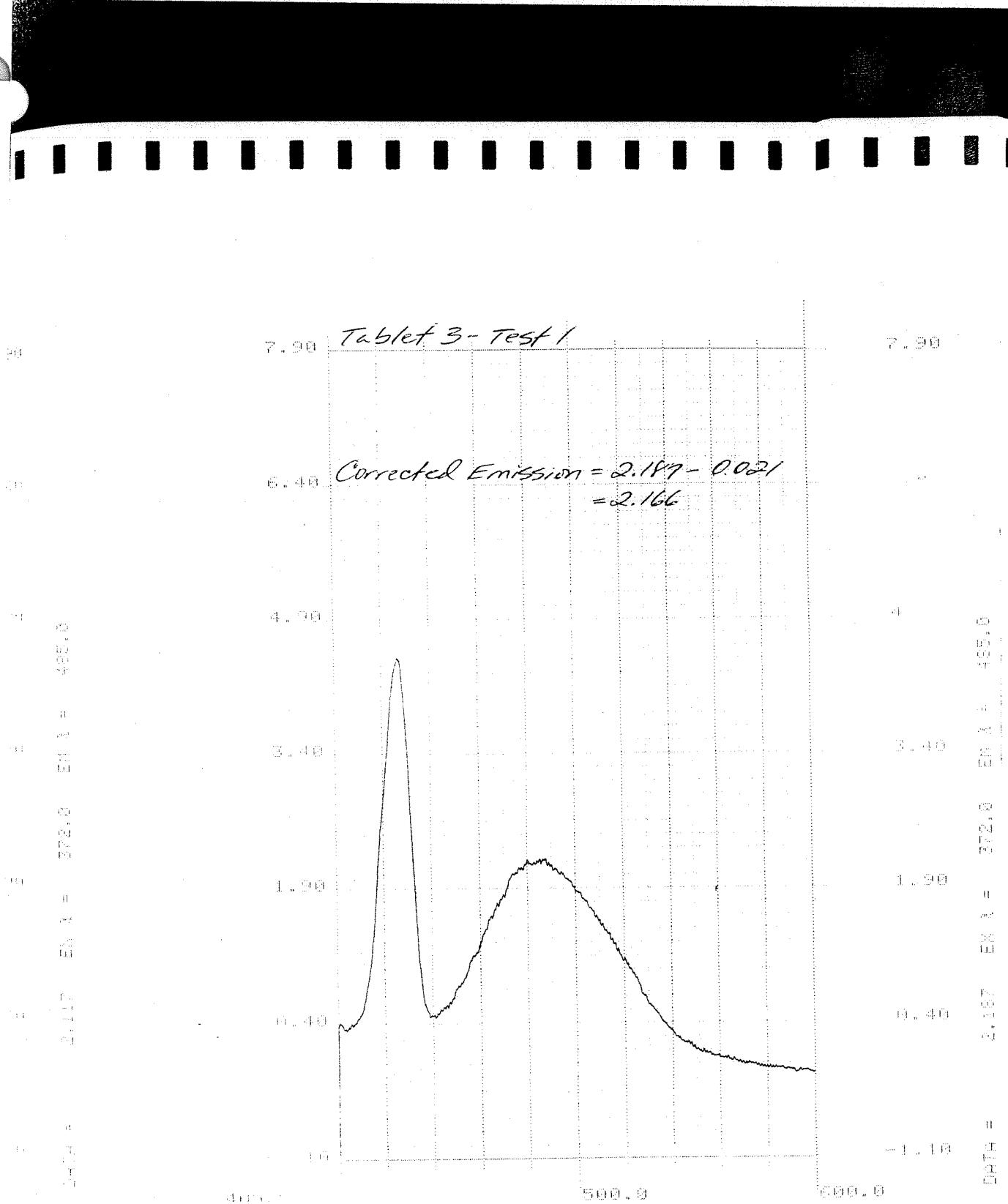


Tablet 1 - Test 2

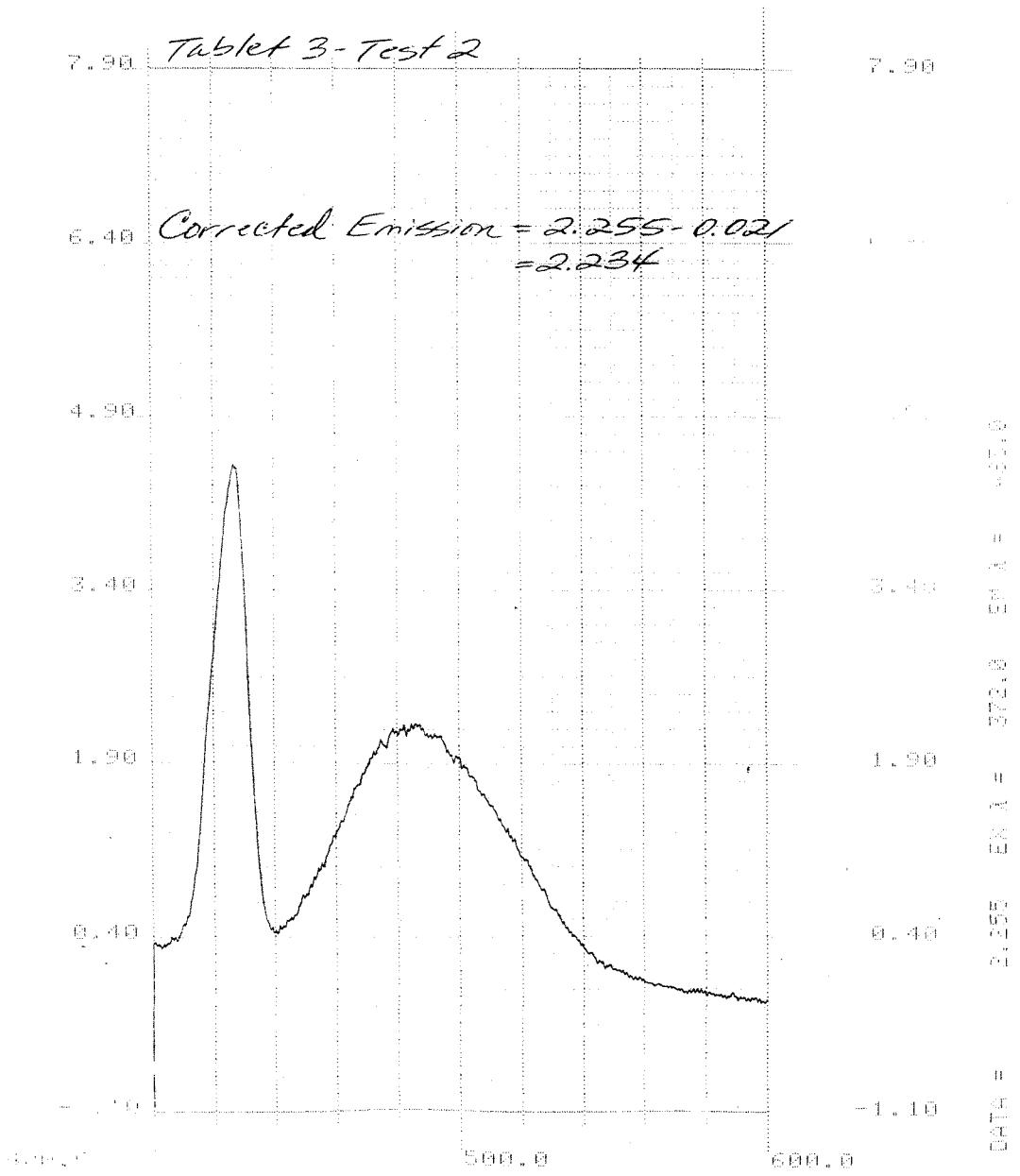




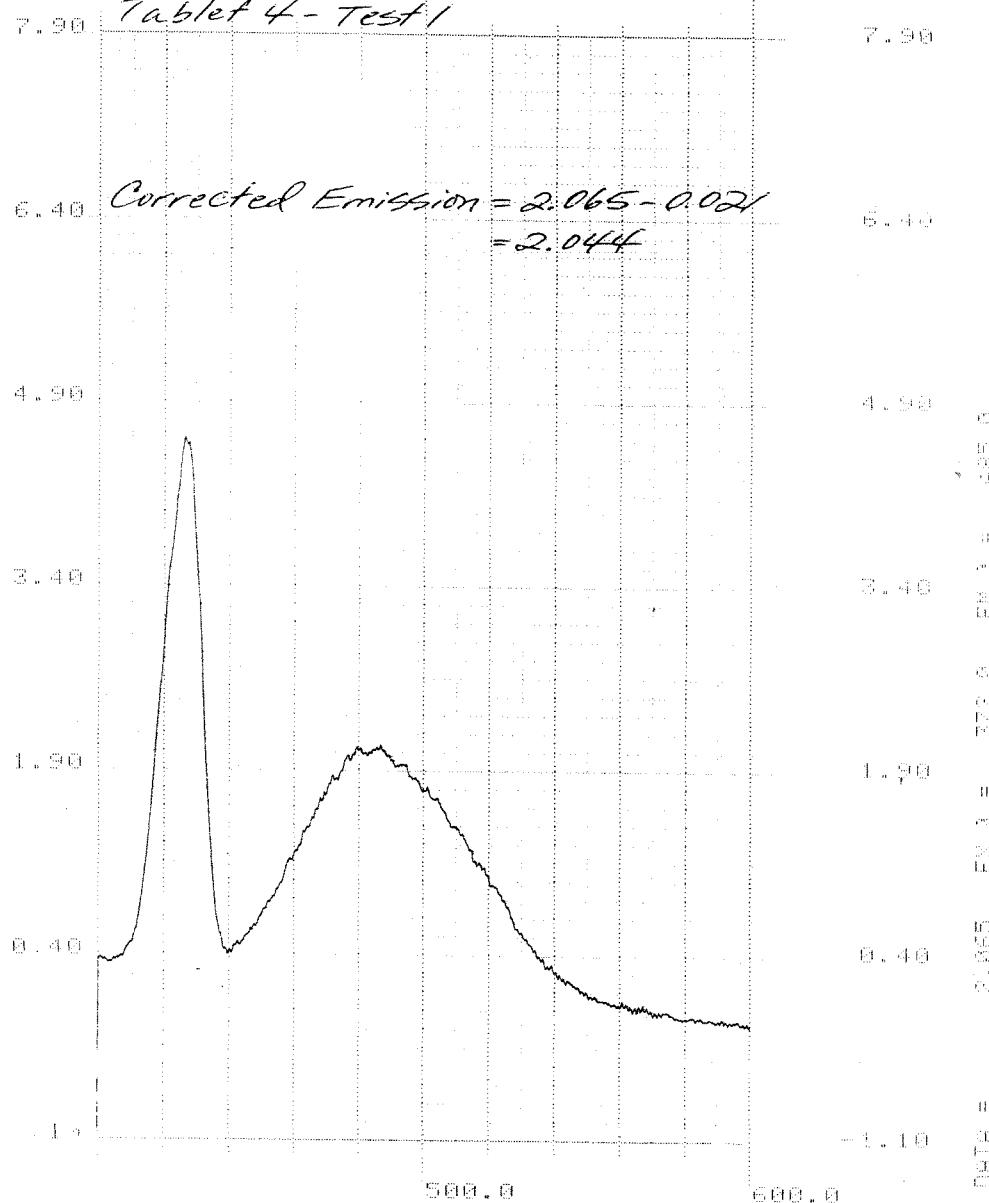




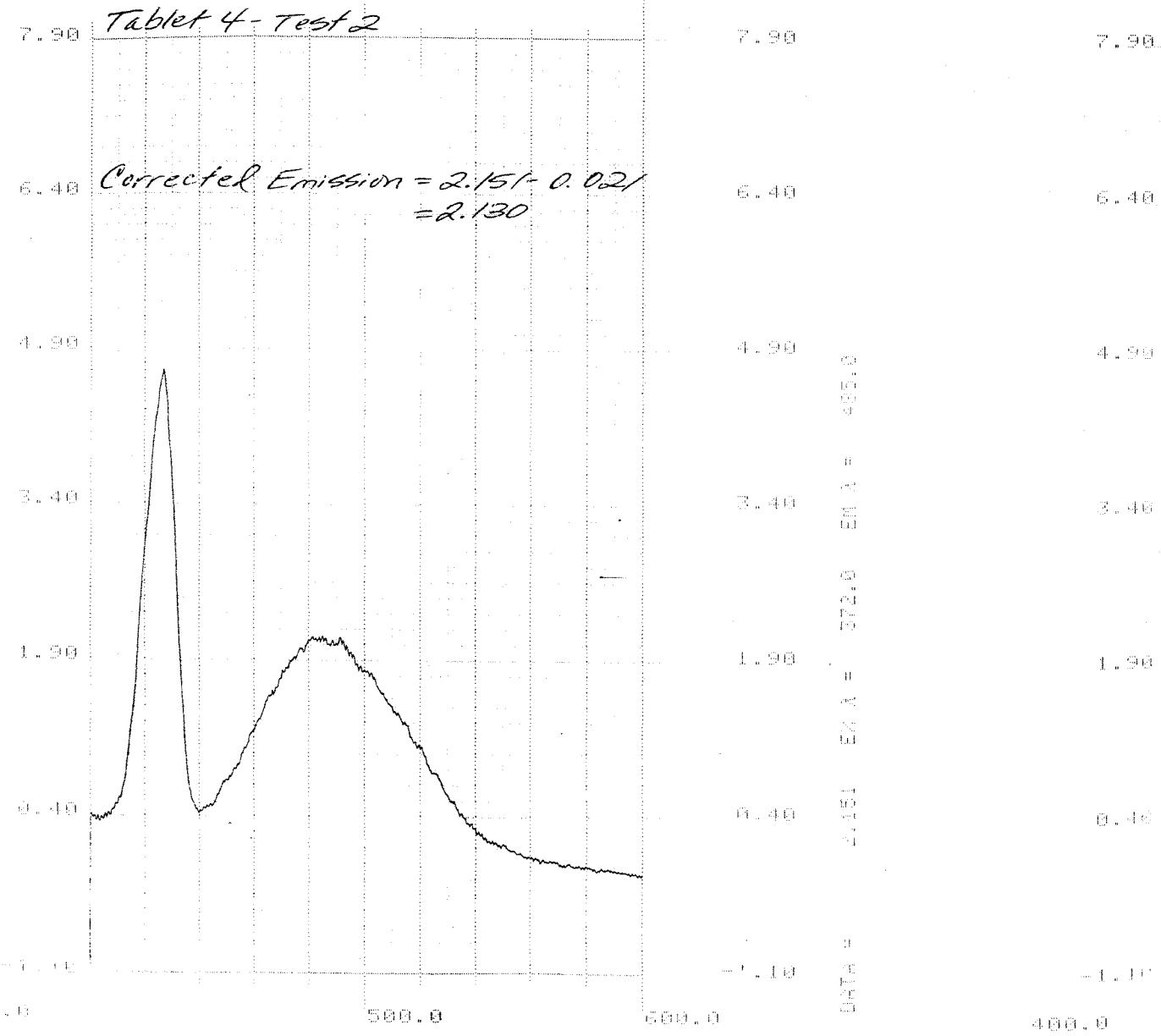
Tablet 3 - Test 2



Tablet 4 - Test 1

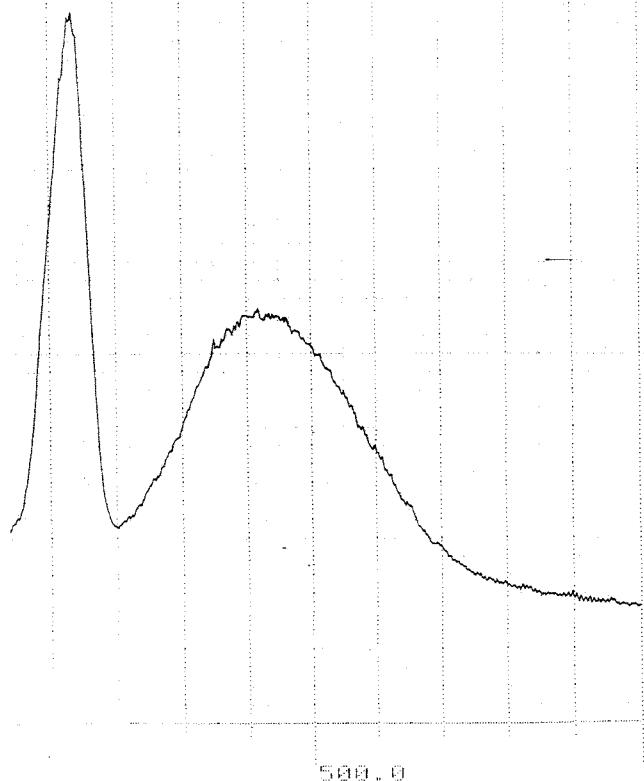


Tablet 4 - Test 2



ublet 5- Test 1

$$\text{Corrected Emission} = 2.208 - 0.021 \\ = 2.187$$



7.90

6.40

4.90

3.40

1.90

0.40

-1.10

7.90

6.40

4.90

3.40

1.90

0.40

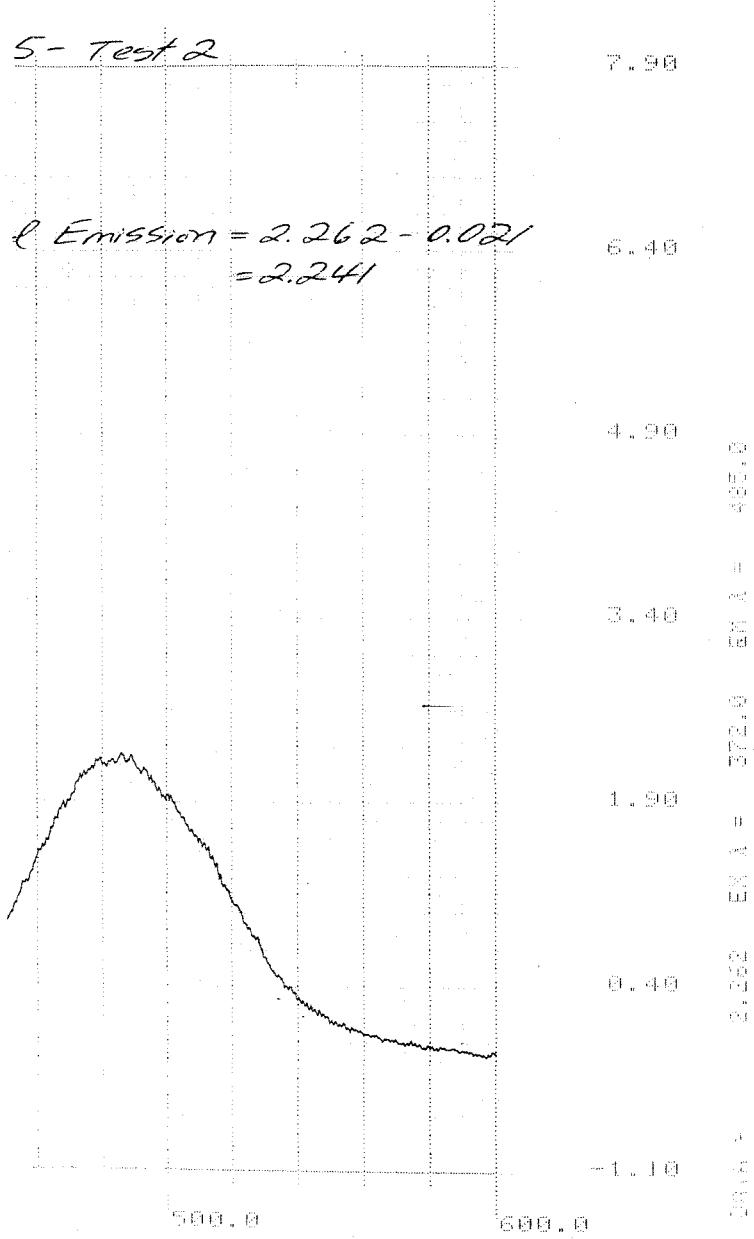
-1.10

Table 1

Corrected

5 - Test 2

$$\text{Emission} = 2.262 - 0.021 \\ = 2.241$$



7.90

6.40

4.90

3.40

1.90

0.40

-1.10

Tablet 6 - Tc

Corrected E

7.90

6.40

4.90

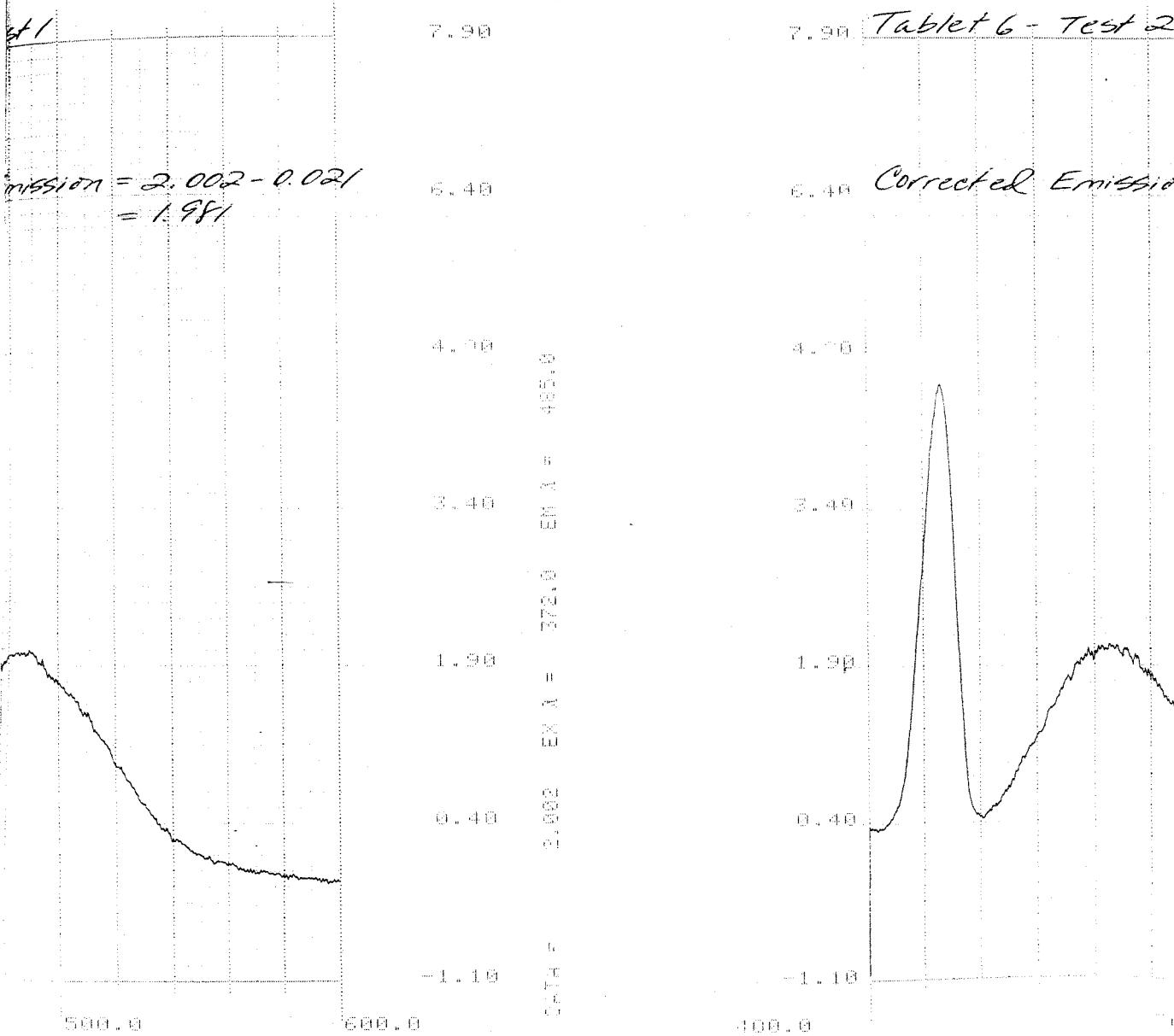
3.40

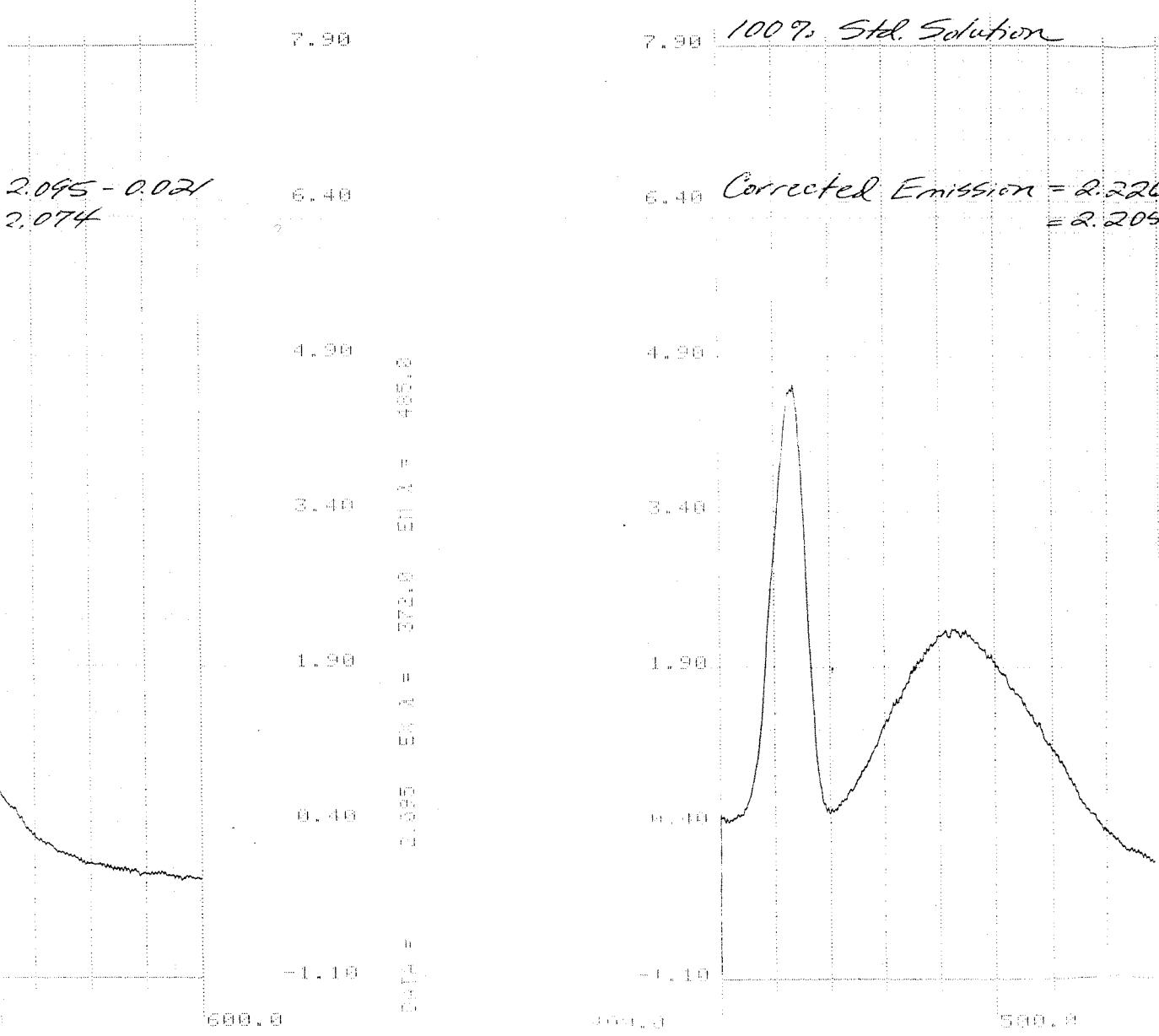
1.90

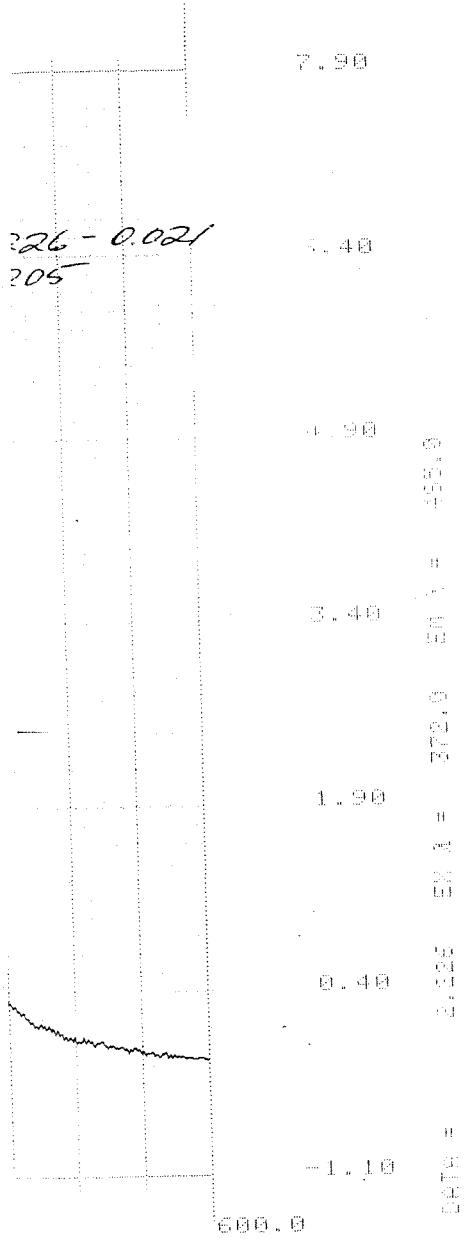
0.40

-1.10

400.0







Digoxin Tablets (0.125 mg)
Spl.# 453913
2/27/08
VF

Labeling

